Full/long title of study	**EVERiST: E**rectile function recovery after bilateral neuro**V**ascular bundle sparing robot assisted radical prostat**E**ctomy in patients with or without an accessory pudendal a**R**tery detected on di**ST**ic multiparametric MRI: A feasibility study
Short title	EVERiST: Impact of image detected accessory pudendal artery on erection recovery after neurovascular bundle sparing prostatectomy.
Version and date of protocol	Version [1.0], [date 07/10/2025]
Sponsor:	University College London (UCL)
Sponsor reference number:	177704
Funder (s):	n/a
IRAS Number:	335003
UCL Data Protection Number:	Z6364106/2024/04/61

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PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Current	1.0	7/10/2025	AA/ZT	Minor wording changes recommended by ethical committee
Previous	0.97	29/8/2025	AA/ZT	Editing after ethical committee feedback
Previous	0.96	27/06/2025	JRO	Minor formatting updates
Previous	0.95	16/12/2024	AA	Proof reading, final references check.
Previous	0.94	12/12/2024	AA/ZT	Final proof reading, layout adjustment.
Previous	0.93	08/12/2024	AA/ZT	Addition of feasibility.
Previous	0.92	6/12/2024	AA/ZT	Final proof reading, amendment of flowchart.
Previous	0.91	25/11/24	AA/ZT	Finalisation of protocol. Inclusion and exclusion criteria finalised. Aligning aims, objectives and primary outcomes. Updates to study flowchart.
Previous	0.9	3/10/24	AA/ZT	Penile doppler inclusion, final wording check. Decision of MR angiography postoperatively. Study flowchart designed.
Previous	0.8	25/9/2024	AA/ZT	Incorporation of MRI angiography postoperatively
Previous	0.7	18/9/2024	AA/ZT	Update with comments after revision
Previous	0.6	10/9/2024	ZT	Suggestion to include PACE tool for video assessment, minor edits

Previous	0.5	7/9/2024	AA	Amended revisions with comments.
Previous	0.4	30/8/2024	ZT	Revision and suggestions for background made
Previous	0.3	16/8/2024	AA	Penile doppler discussion and inclusion
Previous	0.2	28/7/2024	AA	Discussion about included imaging parameters- addition of APA
Previous	0.1	10/7/2024	AA/ZT	Original

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature:  **Date 30/12/2024**

Print Name (in full): ZAFER TANDOGDU

Position: Consultant Urologist and Robotic Pelvic Cancer Surgeon,

Associate Professor (Honorary)

On behalf of the Study Sponsor:

Signature: **Date: 27/06/2025**

Print Name (in full): Pushpsen Joshi

Position: Research Governance Manager

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	335003
REC Reference No.	27703/001
Sponsor Reference No.	177704
Other research reference number(s) (if applicable)	UCL Data Protection number: Z6364106/2024/04/61
Full (Scientific) title	**EVERiST: E**rectile function recovery after neuro**V**ascular bundle sparing robot assisted radical prostat**E**ctomy in patients with or without an accessory pudendal a**R**tery detected on di**a**gno**ST**ic multiparametric MRI: a feasibility study.
Health condition(s) or problem(s) studied	Prostate cancer and erectile dysfunction
Study Type i.e. Cohort etc.	Prospective non-interventional feasibility study
Target sample size	20-40 patients
Aims and Objectives	
aim	The primary aim of this feasibility study is to assess the practicality and acceptability of conducting a full-scale observational study to investigate the influence of imaging detected accessory pudendal arteries (APA) presence on erectile function (EF) outcomes after neurovascular bundle (NVB) sparing robot assisted radical prostatectomy (RARP).
Objectives	
Primary objectives	1. To evaluate the feasibility of recruiting and retaining patients for a study on APA preservation during RARP. 2. To assess the practicality of using pre-operative multi-parametric MRI (mpMRI) for identifying and mapping APAs.
Secondary objectives	1. To determine the feasibility of recording and analysing intraoperative videos for assessing APA preservation during RARP. 2. To explore the acceptability and completion rates of published validated erectile function outcome measures.

	3. To estimate the prevalence of APAs in the study population and the proportion of cases where APA preservation is achievable. 4. To assess the feasibility of collecting quality of life data related to erectile function post-RARP. 5. To identify potential barriers to patient participation and follow-up in a full-scale observational study 6. To gather preliminary data on the variability of erectile function outcomes to inform sample size calculations for a future study.
Outcome Measures	
Primary end-points	1. Recruitment and Retention Rates a) Percentage of patients who satisfy the eligibility criteria amongst patients who opted for RARP b) Percentage of patients consenting to participate (denominator= number of eligible patients approached) c) Percentage of participants completing the study (denominator=number of patients consenting for the study) 2. MRI Assessment Feasibility -Time required for APA mapping on mpMRI 3. Intraoperative Video Analysis -Percentage of RARP procedures with complete, analysable video recordings (denominator= number of patients consenting for the study) -Time required for video analysis of APA preservation 4. Erectile Function Questionnaire Completion -Completion rates of validated EF questionnaires such as the International Index of Erectile Function (IIEF) questionnaire & EPIC -26 sexual domain within patients consenting to join the study. -Time taken to complete the questionnaires 5. Post-operative MRI assessment feasibility -Proportion of patients who accepted to have a 3-month follow-up MRI angiogram within patients consenting to join the study -Proportion of patients who have a patent APA 6. Baseline Penile Doppler US (PDUS) assessment feasibility -Proportion of patients accepting to have a preoperative PDUS. -Proportion of patients who received a baseline Doppler scan. 7. Postoperative PDUS assessment feasibility -Proportion of patients who accepted to have a postoperative PDUS -Proportion of patients who received a postoperative PDUS
Secondary end-points	1. APA Prevalence and Preservation -Percentage of patients with identifiable APAs on mpMRI -Proportion of cases where APA preservation was achieved during RARP

	2. Quality of Life Data Collection -Completion rates of quality-of-life questionnaires related to erectile function -Patient-reported acceptability of quality-of-life assessments. 3. Barriers to Participation -Number and nature of reported barriers to study participation -Reasons for declining participation or withdrawal from the study 4. Variability in Erectile Function Outcomes -Mean and Standard deviation of IIEF scores at follow-up time points -Range of erectile function recovery times
Other outcomes	• Pad free and leak free rate at 12 months. • Clear surgical margin rate (CSM) • Tri-fecta (CSM, Continence & Erectile function)
Eligibility criteria	
Inclusion criteria	• Men diagnosed with cT2-T3a N0 M0 PCa aged between 18 and 79 from all ethnic backgrounds. • Patients who underwent a prostate mpMRI before prostate biopsy. • Medically fit to undergo RARP. • Diagnostic quality prostate biopsies concordant with a diagnostic quality prostate mpMRI adequate to provide a surgical plan. • Scheduled for RARP with a recommendation of NVB spare based on multidisciplinary meetings informed by mpMRI, biopsy result and clinical factors. • Sexually active men with no to mild ED at baseline based on IIEF-EFD (>=24) questionnaire. • Preference to preserve erectile function for sexual intercourse. • Ability to read English sufficiently to understand PIS and able to give informed consent.
Exclusion criteria	• Established moderate/ severe ED (IIEF-EFD <24) • Patients who received neo-adjuvant androgen deprivation therapy. • Patients with previous surgery for benign prostatic enlargement • Patients who received previous treatment for prostate cancer: External beam radiotherapy, brachytherapy, focal therapy, chemotherapy. • Previous pelvic or penile fracture • Previous surgery for ED • Poor quality prostate mpMRI or biparametric MRI (no contrast) • Established vascular disease (ischaemic heart disease, cerebrovascular disease, peripheral vascular disease)
Methodology key points	• Exploratory prospective non-interventional feasibility study to assess the recruitment and retention rates.

	• All patients will have arterial mapping to provide the surgeons with a surgical plan based on the preoperative mpMRI. • Video-recorded BL NVB sparing RARP performed by Mr Ashwin Sridhar, Mr Ben Lamb, Mr Gregory Shaw or Mr Zafer Tandogdu. • All patients will receive the same penile rehabilitation plan that is the standard of care at UCLH. • Patients with an APA identified will be offered a postoperative MRI angiogram to assess patency of APA. • As an optional part to the study, patients will be offered a penile doppler before and/or after their surgery to assess erectile haemodynamics. • The feasibility study will be able to inform the barriers for recruitment in a future appropriately powered study.
STUDY TIMELINES	
Study Duration/length	2 years
Expected Start Date	December 2025
End of Study definition and anticipated date	December 2027 The end of the study is defined as the date of the final 12-month follow-up visit for the last recruited participant. Recruitment will stop once between 20 and 40 patients have been enrolled, and all participants will be followed for 12 months after surgery.
Key Study milestones	Submission for REC and HRA approval Acquire REC and HRA approval Start recruiting patients Complete full 40 patient data with follow-up up to 1 year.
FUNDING & OTHER	
Funding	Non-acquired.
Other support	Clinical research fellow- Abdullah Al-Mitwalli
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	Non-applicable
Data collected / Storage	UCLH/ UCL one drive secure storage data storage
KEY STUDY CONTACTS	
Chief Investigator	Zafer Tandogdu , Honorary Associate Professor z.tandogdu@ucl.ac.uk 02034567898
Study Coordinator	
Sponsor	University College London
Funder(s)	Non
Committees	
Sub-contractors	Non-applicable
Other relevant study personnel	N/A

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work. If further arrangements have been agreed with the funder, please refer to the funding agreement and insert.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

KEY WORDS

“Prostate cancer”

“Erectile dysfunction”

“Robotic Assisted Radical Prostatectomy”

“Magnetic Resonance Imaging”

“Erectile function”

“Surgical quality video assessment”

LIST OF ABBREVIATIONS

PCa: Prostate Cancer

MRI: Magnetic Resonance Imaging

mpMRI: Multi-parametric MRI

RARP: Radical Assisted Radical Prostatectomy

EF: Erectile Function

ED: Erectile Dysfunction

NVB: Neurovascular Bundle

ICI: Intracavernosal Injection

IIEF: International Index of Erectile Function Questionnaire

ICIQ: International Consultation on Incontinence Questionanire

MDT: Multi-Disciplinary Team

CONTENTS

1 INTRODUCTION

Prostate cancer (PCa) is the most common cancer, and the second most common cause of cancer mortality amongst men in the United Kingdom with over 55,000 new patients diagnosed each year(1) . Multi-parametric magnetic resonance imaging (mpMRI) of the prostate has become an established tool for diagnosing PCa, resulting in an image targeted approach to biopsy (2). Diagnosed early, localized PCa can usually be cured with radical treatment such as surgery (radical prostatectomy) or radical radiotherapy(3). Despite the advancements in technique through the adoption of robotic-assisted surgery, there are still significant side effects that persist after radical prostatectomy. These include impairment in sexual function and urinary incontinence (4). These side effects carry a burden on PCa patients and have an impact on their wellbeing and quality of life. Poor sexual function is reported by most PCa patients (5). Every year, around 8,000 patients undergo radical prostatectomy in the National Health Service (NHS) of England. These factors contribute to a decline in psychosexual well-being and overall quality of life. If the nerves and blood vessels that surround the prostate are left intact during surgery (neurovascular bundle sparing), the risk of developing these side effects decreases. The recovery of erectile function (EF) after neurovascular bundle (NVB) sparing surgeries varies and is often unpredictable. The treatment options for erectile dysfunction (ED) after radical prostatectomy involve a systematic progression from medical interventions, such as medications, to intracavernosal injections, and ultimately to invasive treatments, such as the use of a penile prosthesis. The proportion of men who do not recover erections after NVB sparing surgery remains unclear.

It remains uncertain whether the erectile functional impairment after radical prostatectomy is primarily due to vascular or neurogenic changes(6,7). Despite advancements in surgical techniques, including robotic-assisted radical prostatectomy (RARP), that offers improved visualization and tissue handling, recovery of EF continues to be poor, even when the NVB is preserved. A significant factor contributing to this issue may be the need for further refinement of NVB preservation techniques. Current NVB-sparing procedures typically focus on the bundle located behind the prostate, extending from the base to the apex. However, pelvic vascular anatomy can vary in up to 38% of patients, and these variations may be overlooked in conventional NVB-sparing approaches, potentially contributing to ED (8).

We now have an opportunity to map the details of pelvic vasculature and its relationship to the prostate and penile blood supply. This can be accomplished through the high-resolution mpMRI scans that are now a standard part of the PCa diagnostic pathway. Furthermore, robotic-assisted surgery offers a unique chance to record the intracorporeal surgical procedure, allowing for detailed review of the technical steps taken during the operation. This recording capability is crucial for analysing whether arteries outside the conventional neurovascular bundle sparing planes are inadvertently sacrificed during surgery. By correlating these surgical recordings with pre-operative mpMRI scans and post-operative EF outcomes, we can gain insights into the vascular anatomy variations and their impact on EF preservation.

This study aims to assess the feasibility and practicality to examine the influence of imaging detected accessory pudendal arteries (APA) presence on EF outcomes after BL NVB sparing RARP, with the objective of guiding surgical decision-making.

1.1 Lay Summary:

Prostate cancer is the most common cancer among men in the UK, with main treatment options for localized disease being robotic prostatectomy or radical radiotherapy. Sexual side effects are significant concerns that can greatly impact a patient's wellbeing and quality of life. While surgeons use techniques like neurovascular bundle sparing to minimize these effects, the success rates vary, making it challenging to provide personalized counselling before surgery. This uncertainty, coupled with difficulties in managing post-surgery sexual issues, can lead to patient disengagement from healthcare. Providing patients with personalized predictions before surgery could help set appropriate expectations regarding the likelihood and duration of recovery, potentially improving decision-making, preparation, and ongoing engagement with post-treatment care. This approach may lead to better overall outcomes and patient satisfaction in prostate cancer treatment.

The mechanism of erectile dysfunction after surgery is not fully understood as some patients recover their erections naturally soon after surgery whilst, the majority of patients will require treatment in the form of medication or injection to maintain their erections in the first year. This may be related to an additional artery to the penis that is present is up to a third of patients. With the improvement in imaging to diagnose prostate cancer, we now can identify which patients have these additional arteries to the penis.

We believe that preserving these additional arteries will be good for patient's erection recovery however, no one has ever independently looked at whether the surgery indeed preserves the additional blood vessels that supply the penis. Additionally, the impact of this on erection recovery after surgery is not fully known and is under debate. These vessels can be different in each patient and might not always be where surgeons typically look to preserve them. We plan to map out each patient's blood vessels and compare this to videos of their surgery to see how well they match up. Lastly, earlier studies haven't collected data in a thorough way. Our study will focus on men who had good sexual function before surgery and whose surgeons tried to preserve the nerves and blood vessels during the operation. By addressing these issues, we hope to create a more accurate way to predict and understand sexual function after prostate surgery, which could help patients make better-informed decisions about their treatment.

The main aim of this study is to understand whether it is feasible to conduct a large study looking at the impact of these additional arteries to erection recovery after robotic radical prostatectomy surgery for prostate cancer. Our goal is to assess whether it is possible to study the impact of preserving these arteries on patient's ability to have adequate erections for sexual activity and assess the impact of preservation of these arteries on the patient's quality of life. This knowledge is intended to inform a larger study which may improve patient's decision making before their surgery and set realistic expectations for erection recovery after surgery.

1.2 BACKGROUND AND RATIONALE

PCa is the second most common cancer in men, with an estimated 1.4 million diagnoses and accounting for 375,000 deaths worldwide in 2020 (1,9). mpMRI has become an established tool for diagnosing PCa (10), allowing an image-targeted approach to biopsy(11). For men with a life

expectancy of more than 10 years who have localised intermediate- or high-risk PCa, the European Association of Urology (EAU) recommends radical treatment such as surgery or radiotherapy(12). Among the surgical options, robot-assisted radical prostatectomy (RARP) has become the mainstay procedure. However, the long-term adverse effects following RARP, namely ED and urinary incontinence, significantly impact the quality of life for PCa survivors (4,13,14).

The EF recovery after RARP has been studied extensively however, the ideal preoperative planning and surgical technique to abolish ED remains elusive. This is likely to be related to multiple factors. It is important to outline what is known with regards to the pathophysiology of ED, advancements in imaging diagnostics, surgical techniques developed to mitigate the risks, and the tools used to capture the functional and quality of life aspects of erectile loss. These factors will be summarised in the next subheadings.

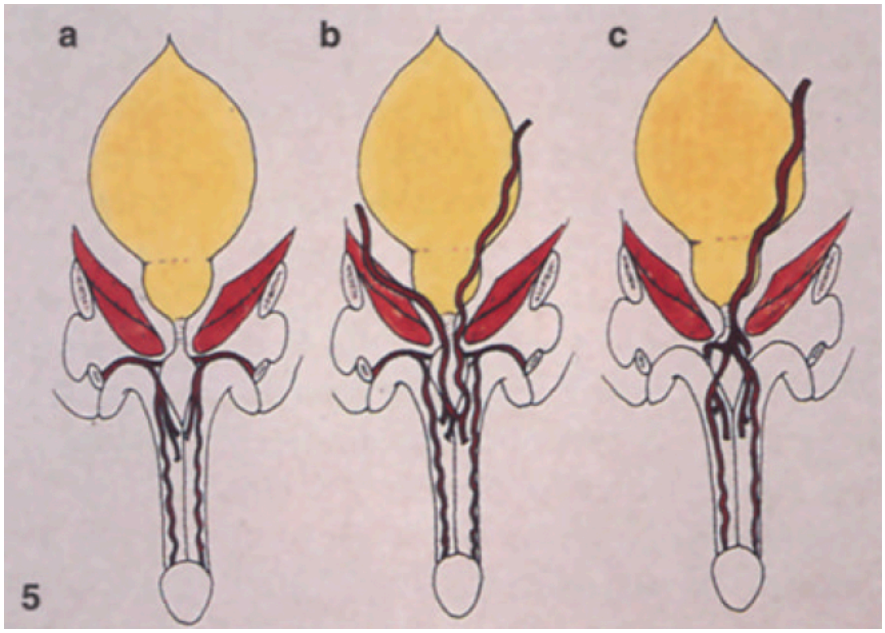
1.2.1 Mechanism of ED after RARP

The proposed pathophysiology of ED following radical prostatectomy is multifaceted and involves several interlinked mechanisms including neurogenic, vascular and fibrotic factors.

Neuropraxia relating to cavernous nerve injury occurs during surgery where the NVB is injured due to cutting, coagulating, traction or compression injury. (15–17) The neuropraxia leads to local hypoxia and this reduces nitrous oxide production and inhibits release of prostaglandin which has an antifibrotic effect. Subsequently, impairment of smooth muscle relaxation in the corpus cavernosum occurs leading to veno-occlusive dysfunction and fibrotic changes ensue.

It is important to outline the arterial supply to the penis which has been described and classified using cadaveric dissection as outlined in figure 1 below taken from Droupy et al (18). This shows the 3 categories as:

a. Penile arterial supply purely from the internal pudendal artery (IPA)
b. Penile arterial supply from both the IPA and accessory pudendal artery (APA)
c. Penile arterial supply purely from APA.



Vascular compromise plays a role in ED after RARP which may itself cause arterial insufficiency and subsequent hypoxia. APA injury during surgery is thought to cause the vascular compromise. (17) APA may have role in preserving EF and promoting recovery after radical prostatectomy. (19). It is most likely that a combination of factors influences the EF outcome but as a higher degree of both neural and vascular components are preserved the likelihood of functional recovery increases. It can also be postulated that in the absence of adequate arterial flow, which can be compromised through surgery, the extent of tissue ischaemia will override any neural recovery. As such the arterial supply is a must for prevention of any ischemia.

Initial studies found that preservation of APA lead to better recovery for EF however, subsequent studies have demonstrated that transecting the APA during radical prostatectomy had no impact on EF recovery after surgery. All these studies identified these vessels during surgery without a preoperative mapping of the vasculature (20,21). There was risk of selection bias without accounting for important confounders such as objective quality of nerve spare surgery. There are clearly conflicting evidence and the need for a prospective study assessing the effect of APA preservation on EF recovery after RARP.

In previous studies that assessed the effect of APA preservation on EF recovery after radical prostatectomy relied only on intraoperative identification of these arteries. It is clear from other previous literature, that studies utilising imaging or cadaveric dissection identified higher prevalence of APAs that those relying on intraoperative identification during surgery (8).

We hypothesise that collateral circulation to the penis through a preserved APA after radical prostatectomy leads to an improved of EF recovery than in patients without APA. The collateral circulation may lead to improved mechanism for recovery after the stress of surgery.

1.2.2 NVB sparing surgery and other surgical techniques to improve EF

The concept and technique of NVB sparing surgery was first introduced by Walsh et al in 1982 where the standard radical surgical technique was modified to preserve the NVB that runs alongside the prostate (on the posterolateral aspect) (22,23). This did improve the EF recovery after surgery however it did not abolish it.

The evolution of NVB sparing techniques has seen significant advancements over the years. The original NVB sparing procedure described utilized an interfascial technique. However, recent studies have discovered presence of additional nerve fibres on the anterolateral surface of the prostate. This prompted development of the intrafascial technique, which aims for more meticulous dissection (24).

The interfascial approach involves dissecting between the prostatic capsule and the endopelvic fascia, preserving the main neurovascular bundles located posterolaterally to the prostate. In contrast, the intrafascial technique is characterized by:

1. dissection on the prostatic capsule

2. Minimal to no additional tissue remaining over the prostate at conclusion of RARP

This refined approach aims to maximize NVB preservation, potentially leading to improved functional outcomes for patients undergoing radical prostate surgery.

Moreover, the EF recovery after NVB sparing radical prostatectomy in literature varies widely (25). A systematic review and meta-analysis showed the EF recovery at 1 year for patients undergoing bilateral NVB spare prostatectomy ranges between 43% to 89%(26).This variation is partly due to the extent of the NVB spare which has been described before as intrafascial spare and intrafascial spare(27). This variability can be attributed to several factors, including surgical reporting bias, a lack of standardization in surgical techniques, and studies that have not adequately addressed confounding variables.

Lately a further surgical technique in preserving the anterior fascial during RARP has been developed (28). This technique had become possible with the robotic tools allowing the surgery to be conducted without going over the bladder but instead to work within the space behind the bladder and prostate. The technique, which preserves structures anterior to the prostate have shown earlier continence recovery rates than anterior standard approach although EF recovery rates have been comparable thus far between the two approaches (29). Yet these outcomes also suffer from similar limitations of previously reported anterior approach.

At University College London Hospital, a weekly MRI planning meeting is held to review all patients on the waiting list for RARP. During this meeting, an expert uro-radiologist assesses each case, resulting in a recommendation for non-NVB, unilateral NVB, or bilateral NVB-sparing surgery.

1.2.3 Quality of NVB spare surgery and video assessment

The LAPPRO study highlights significant variation in functional and oncological outcomes among surgeons performing radical prostatectomy, emphasizing the influence of surgeon-specific factors such as experience, surgical technique and volume. These disparities persisted even after accounting for patient and tumour characteristics, again highlighting the influence of technique (30).

Heterogeneity in EF recovery seen suggests there are variations in surgical techniques employed by different surgeons. For instance, a recent study using video analysis of RARP revealed that the technique is not standardised among surgeons (31). Global evaluation of robotic skills during RARP through peer- reviewed video assessment has been demonstrated in previous studies (32). A validated tool, prostatectomy assessment and competency evaluation (PACE) has been developed to evaluate the expertise of surgeons performing RARP (33). To our knowledge, there has not been an evaluation of the quality and grade of NVB preserving surgery to assess the relationship with functional outcomes using a structured framework.

A structured assessment of the surgical technique using the recorded videos will help identify the techniques leading to better functional outcomes.

1.2.4 Preoperative mpMRI, mapping of pelvic vasculature and postoperative MRI

mpMRI is accepted as the gold standard for preoperative local staging of PCa. In addition to diagnosis and staging, mpMRI helps guide surgery and the degree of NVB sparing without impacting margin status (34).

Prior research in this area has focused on utilising the pre-surgical mpMRI information to predict the recovery of continence(35). For example, membranous-urethral length (MUL), measured using the preoperative mpMRI, is an established independent predictor for postoperative recovery of urinary continence (36,37). This information informs preoperative patient counselling and treatment decision-making. However, the literature on imaging markers to predict and mitigate the risk of ED in patients with PCa undergoing minimally invasive radical prostatectomy has not been summarised before.

We carried out a systematic review (PROSPERO; Registrations ID CRD 42022359557) to evaluate the possible application of imaging parameters to predict EF after RARP. Nevertheless, the variability of results, significant risk of bias, and inadequate study design in the available literature render the therapeutic use of the reported parameters of low utility. Good-quality, prospective research is needed to further evaluate a variety of imaging parameters as predictors of postoperative EF to ensure results are reproducible. There has been no assessment of accessory pudendal artery identification through imaging preoperatively and correlation of this to EF outcomes after surgery. The prevalence of accessory pudendal artery is 38.2% (8). In our studies at UCLH we were able to map the accessory pudendal arteries of men using prostate mpMRI (unpublished material). We are currently looking at identifying the accuracy of the mpMRI in identifying the APA (unpublished material).

Several studies have shown that vasculature of the pelvis can be mapped. Selective pudendal angiography can be used to demonstrate the presence of accessory pudendal arteries; however, this is an invasive procedure (38). Moreover, contrast enhanced MR angiography can be used to identify accessory pudendal arteries(39).

The dynamic contrast enhancement sequence is performed as part of the mpMRI for PCa diagnosis in everyday routine practice. This can be used to map the vasculature of the prostate identifying the presence of accessory pudendal arteries. In our study we will map the accessory pudendal arteries using the diagnostic prostate mpMRI. This information will be shared with surgeons to guide their surgery, and we will review the implications of EF recovery.

One study looked at difference in anatomical changes between preoperative and postoperative MRI scan in relation to postoperative urinary incontinence outcome(40). This helped outline the anatomical changes associated with better urinary function. In our study, by obtaining an additional MR angiogram at 3 months after surgery for patients who we detected an accessory pudendal artery, we will be able to assess whether the accessory blood supply to the penis was preserved or injured and assess its correlation with EF recovery.

1.2.5 Standard of care for ED after RARP

Penile rehabilitation is the term often used to describe the treatment for ED after PCa treatment. The standard of care for the treatment of penile rehabilitation after RARP is a stepwise approach. Initially, all patients are offered phosphodiesterase 5 inhibitors (PDE5i) in the form of either tadalafil or sildenafil. Alongside this, penile rehabilitation using a vacuum erection device is recommended to maintain penile length and offers an opportunity for motivated patients to resume sexual activity with the application of the ring. Patients with persistent ED despite medical treatment are offered second line treatment in the form of ICI using alprostadil (PGE1) or Invicorp

(Aviptadil/Phentolamine). This is self-administered by the patient in clinic setting after a tutorial in the andrology clinic. If the above measures fail, patients are ultimately offered penile prosthesis surgery however, this is after at least 18 months to allow for erectile recovery to take place after surgery.

1.2.6 Assessment of functional outcomes after RARP

A. Through Validated EF questionnaire

The assessment and treatment of ED has been greatly improved with the introduction of EF validated questionnaires over the last 3 decades namely the international index of EF (IIEF). Such questionnaires were designed to screen for ED and assess the efficacy of the oral medication in treating ED (41). Several forms of the IIEF are available and it includes an EF domain (IIEF-EFD), sexual desire domain, intercourse satisfaction and overall satisfaction domains. Another widely used bothersome score is the disease specific expanded prostate cancer index composite (EPIC) (42). The EPIC questionnaire was designed to assesses symptoms of PCa treatment including both radiotherapy and surgery sequalae.

B. Penile doppler assessment of erectile hemodynamics.

An objective method to assess EF is the use of penile dopplers ultrasound (PDUS). A study by Mulhall et al, conducted PDUS on patients who underwent bilateral NVB sparing radical prostatectomy, it was found that 32% of men exhibited normal erectile haemodynamics following the surgery (43). These 32% had a statistically significant higher IIEF scores, penile rigidity and functional erections allowing intercourse than those with abnormal haemodynamics.

A subset of patients exhibits evident vascular alterations following radical prostatectomy. Thus far, all studies have focused on either identification of accessory pudendal artery (19) or carrying out PDUS for the assessment of the vascular haemodynamic after surgery (43) but never in the same study as prior research was in the pre mpMRI era. Consequently, understanding the pudendal artery and its anatomical variations, along with their preservation in patients experiencing erectile dysfunction following RARP, necessitates an evaluation of whether penile circulation is likewise maintained. This will signify the presence of continuous neuropraxia and an expected recovery over time.

PDUS are carried out after an Intracavernosal injection (ICI) of an erection inducing medication mostly commonly alprostadil or Invicorp. As an optional part of the study, we will offer patients undergoing RARP a PDUS to assess their erectile hemodynamics before and after their surgery. For patients who fail to respond to first-line oral medication for ED, ICI medications are the second-line treatment for motivated patients. A PDUS can be carried out simultaneously to evaluate erectile hemodynamics which is currently the standard of care to investigate and prognosticate erectile dysfunction.

1.2.7 Summary

The proposed pathophysiology for EF is complex and likely involves both neurogenic and vasculogenic components. Despite advancement in surgical technique with the widespread adoption of robotic surgery, EF recovery after NVB bundle sparing surgery remains unclear. With the widespread adoption of the mpMRI, specifically the dynamic contrast enhancement sequence, radiologists can map the vasculature of the pelvis, and this information may be useful in guiding surgery and improving EF outcomes. Video recordings of robotic surgery also offer the opportunity to objectively assess the operative technique and correlate this to functional outcomes. Our objective is to enhance patient outcomes by furnishing surgeons with the necessary information regarding patient-specific accessory pudendal arteries, which will be mapped to facilitate surgery with preservation of these arteries.

The literature suggests that the quality of NVB sparing may be the cause of variation in EF recovery. (30). To ensure we capture this confounder in our outcome measurement of EF recovery we will assess the quality of the NVB sparing using a validated tool(33).

Measurement of EF recovery has also been a topic of debate and despite there are patients reported outcome measure tools namely EPIC-26 and IIEF-EFD we are unsure if these measures represent what patients value most(4). We therefore will capture EF recovery using validated tools and objectively using PDUS.

We believe that the pathophysiology of EF recovery following RARP is a combination of arterial supply impairment and neuropraxia. It is believed that neuropraxia recovery can persist for up to 24 months following RARP(44). Nevertheless, it is crucial for management purposes to ascertain whether the arterial supply is secure, and the gold standard measurement is a PDUS. This will be provided to our patients as an optional assessment.

1.2.7 Feasibility assessment

This study will assess the practicality, acceptability and feasibility to conduct a full-scale observational study to investigate the influence of imaging detected APA on the EF recovery after NVB sparing RARP. This study will set out to assess barriers in recruitment, rate limiting steps, and the feasibility of utilising the current preoperative mpMRI in detection of APA in patients undergoing RARP and the practicality of carrying out PDUS and postoperative MRI angiogram to assess APA patency. This will inform a future appropriately powered study examining the effect of APA preservation on dual assessed EF recovery after NVB sparing RARP.

2 AIM(S),OBJECTIVES, AND OUTCOMES

Theory:

The accessory pudendal artery is regarded as a supplementary supply to the corpus cavernosum, providing improved physiological support for erectile function through collateral arterial supply. This results in increased resilience to external stress, allowing patients with APA to better endure RARP-induced stress as compared to patients without APA.

Hypotheses

Imaging-based detection of the APA will aid in its preservation and exhibit superior EF recovery compared to those without APA and those with APA that was not preserved after surgery.

Aims and Objectives	
aim	The primary aim of this feasibility study is to assess the practicality and acceptability of conducting a full-scale observational study to investigate the influence of imaging detected accessory pudendal arteries (APA) presence on erectile function (EF) outcomes after neurovascular bundle (NVB) sparing robot assisted radical prostatectomy (RARP).
Objectives	
Primary objectives	1. To evaluate the feasibility of recruiting and retaining patients for a study on APA preservation during RARP. 2. To assess the practicality of using pre-operative multi-parametric MRI (mpMRI) for identifying and mapping APAs.
Secondary objectives	1. To determine the feasibility of recording and analysing intraoperative videos for assessing APA preservation during RARP. 2. To explore the acceptability and completion rates of published validated erectile function outcome measures. 3. To estimate the prevalence of APAs in the study population and the proportion of cases where APA preservation is achievable. 4. To assess the feasibility of collecting quality of life data related to erectile function post-RARP. 5. To identify potential barriers to patient participation and follow-up in a full-scale observational study 6. To gather preliminary data on the variability of erectile function outcomes to inform sample size calculations for a future study.
Outcome Measures	
Primary end-points	1. Recruitment and Retention Rates a) Percentage of patients who satisfy the eligibility criteria amongst patients who opted for RARP b) Percentage of patients consenting to participate (denominator= number of eligible patients approached) c) Percentage of participants completing the study (denominator=number of patients consenting for the study) 2. MRI Assessment Feasibility -Time required for APA mapping on mpMRI 3. Intraoperative Video Analysis

	-Percentage of RARP procedures with complete, analysable video recordings (denominator= number of patients consenting for the study) -Time required for video analysis of APA preservation 4. Erectile Function Questionnaire Completion -Completion rates of validated EF questionnaires such as the International Index of Erectile Function (IIEF) questionnaire & EPIC -26 sexual domain within patients consenting to join the study. -Time taken to complete the questionnaires 5. Post-operative MRI assessment feasibility -Proportion of patients who accepted to have a 3-month follow-up MRI angiogram within patients consenting to join the study -Proportion of patients who have a patent APA 6. Baseline Penile Doppler US (PDUS) assessment feasibility -Proportion of patients accepting to have a preoperative PDUS. -Proportion of patients who received a baseline Doppler scan. 7. Postoperative PDUS assessment feasibility -Proportion of patients who accepted to have a postoperative PDUS -Proportion of patients who received a postoperative PDUS
Secondary end-points	1. APA Prevalence and Preservation -Percentage of patients with identifiable APAs on mpMRI -Proportion of cases where APA preservation was achieved during RARP 2. Quality of Life Data Collection -Completion rates of quality-of-life questionnaires related to erectile function -Patient-reported acceptability of quality-of-life assessments. 3. Barriers to Participation -Number and nature of reported barriers to study participation -Reasons for declining participation or withdrawal from the study 4. Variability in Erectile Function Outcomes -Mean and Standard deviation of IIEF scores at follow-up time points -Range of erectile function recovery times
Other outcomes	• Pad free and leak free rate at 12 months. • Clear surgical margin rate (CSM) • Tri-fecta (CSM, Continence & Erectile function)

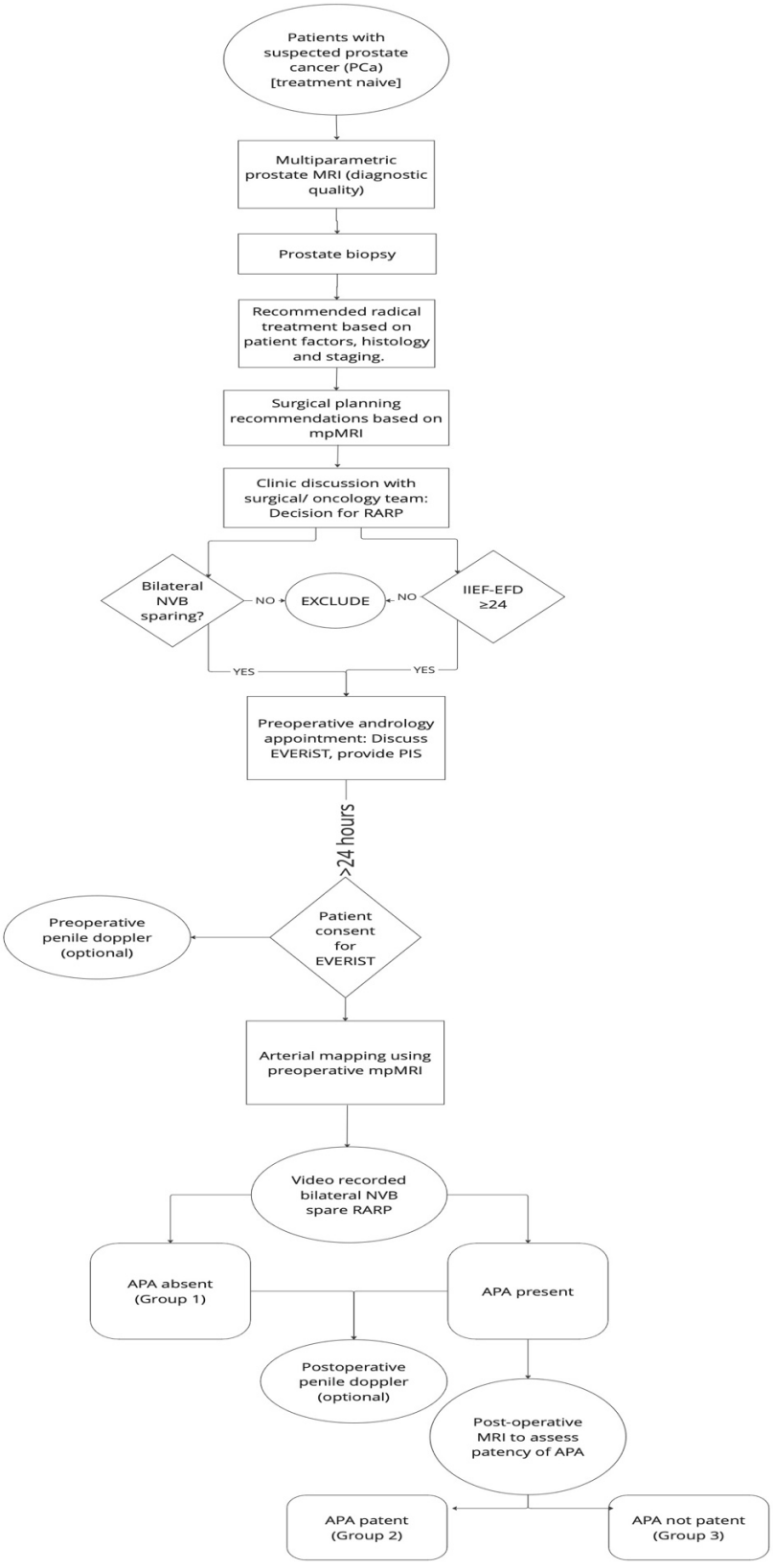
3 STUDY DESIGN & METHODS OF DATA COLLECTION

This is a prospective single centre non-interventional feasibility study. This research will recruit from patients with localized PCa waiting for RARP at University College London Hospitals.

In this prospective feasibility study, we will obtain patient demographic/ medical history and outline imaging parameters from the preoperative mpMRI. Functional outcomes will be measured using validated PROMs and an optional penile doppler for patients who prefer to have intracavernosal injections to treat their erections.

We aim to approximately recruit 20-40 patients into our research study. The study will include individuals in their 18 or older. We will recruit patients who have good EF based (IIEF-EFD >=24, PDE5i naive) prior to the procedure. Patients undergoing bilateral NVB spare RARP will have the opportunity to participate in this research if they wish. The eligibility criteria are discussed in detail in section 6. All patients will have IIEF-EFD and EPIC -26 completed prior to surgery and 6 weeks, 6 and 12 months.

FIGURE 2 shows the the recruitment process as well as the timeline of this prospective non-interventional study


Patients with suspected prostate cancer (PCa) [treatment naive]
Multiparametric prostate MRI (diagnostic quality)
Prostate biopsy
Recommended radical treatment based on patient factors, histology and staging.
Surgical planning recommendations based on mpMRI
Clinic discussion with surgical/ oncology team: Decision for RARP
Bilateral NVB sparing?
NO
EXCLUDE
NO
IIEF-EFD ≥24
YES
YES
Preoperative andrology appointment: Discuss EVERiST, provide PIS
>24 hours
Patient consent for EVERIST
Preoperative penile doppler (optional)
Arterial mapping using preoperative mpMRI
Video recorded bilateral NVB spare RARP
APA absent (Group 1)
APA present
Postoperative penile doppler (optional)
Post-operative MRI to assess patency of APA
APA patent (Group 2)
APA not patent (Group 3)

Participants will join the study with at least 24 hours to review the information sheet and provide consent to be part of the research project.

Sampling strategy:
Our study will employ a consecutive sampling approach over a 12-month period. All consecutive patients in that timeframe who are eligible to participate in the study will be offered to join the study.

Study duration: Recruitment will be for 12 months and at duration will be least 12 months for the primary outcome with a secondary outcome at 24 months follow-up.

3.1 Data collection:

We will collect the following data and keep a log about the number of patients:

1. eligible for the study
2. consenting to be enrolled in the study
3. completing all baseline questionnaires, questionnaires at the set time points.
4. consent and undertake a PDUS at baseline
5. with successful intracorporal video retrieval during RARP
6. consent and undertake a PDUS postoperatively
7. consent and undertake an MRI angiogram postoperatively

Data will be collected through:

1. Review of patient medical and operative hospital records: Standardized data collection forms: will be used to record observations and extract data from medical records.
2. Direct patient observation: Patients will be followed for at least 12 months
3. pre-surgical prostate mpMRI
4. surgical video recordings
5. Functional outcomes including EF and continence using validated tools at baseline and 6 weeks, 6, 12 and 24 months.
6. Postoperative MRI for patients with an APA identified.
7. Optional: pre and postoperative penile doppler US

3.2 Data variables:

List the variables to be collected:

A. Ethnicity, occupation, age.
B. Past medical and surgical history (hypertension, diabetes, high cholesterol, obstructive sleep apnea, previous prostate benign surgery, smoking history and pack years, medications exclusions: IHD, CVA, PVD)
C. body mass index
D. blood tests to diagnose any metabolic cause for ED
    a. lipid profile
    b. testosterone
    c. HbA1c
E. Assessment of preoperative mpMRI (see section 3.3)
F. Operative documentation:
    a. Time in minutes, blood loss

b. Nerve spare grade
    i. Laterality
    ii. Interfascial vs intrafascial
    iii. High or low release
c. Different surgical approaches (yes or no) Anterior fascial spare, bladder neck spare, complete urethral preservation, intraprostatic urethral preservation, Mansouri approach.

G. Assessment of intracorporal video recordings (see section 3.4)
H. Functional outcomes using validated tools (see section 3.5)
I. Oncological outcomes i.e. final histology, post-operative PSA and salvage treatment if any.
J. Postoperative MRI angiogram for patients with APA (see section 3.7)
    a. Vasculature assessment postoperatively
K. Optional: assessment of erectile haemodynamics (see section 3.8)
    a. Peak systolic velocity and end diastolic velocity
    b. Before and after RARP

3.3 Assessment of preoperative mpMRI:

The pelvic vascular anatomy exhibits significant variations among individuals, which will be mapped out during this study using the diagnostic preoperative mpMRI. Existing classification systems will be used to categorize the origin, trajectory, dimensions, and branching patterns of the prostate arteries, pudendal arteries, and other accessory arteries supplying the penis (18,45).

This will be carried out by at least 2 blinded dedicated uro-radiologists with expertise in interventional vascular radiology and PCa. The assessors will be blinded to the patient, operative details, surgeon and functional outcomes of the surgery.

The MRI quality will be outlined mainly through assessment of the dynamic contrast enhancement sequence. Poor quality MRI will be excluded from the study based on enhancement phase field of view and ability to visualize contrast up to the cavernosal arteries.

List of variables collected through pre-operative MRI review and surgical planning parameters by two expert uro-radiologists:

a. Prostate volume
b. Prostate morphology (median lobe)
c. findings related to difficult dissection i.e. pelvic lipomatosis, fistulas, pelvic fractures
d. Pudendal artery presence and diameter
e. Prostate artery presence and classification
f. Accessory pudendal artery presence and origin
g. Cavernosal arteries

The resulting classification will be displayed in a tabular format, facilitating visualization and comparison of the variations noted among different subjects. These categories will be used to examine their association with EF recovery and treatment response at 6 weeks, 6 months and 12 months.

3.4 Assessment of intracorporal video recordings:

The outcomes of EF recovery are influenced by the quality of NVB sparing surgery. This has the potential to confound our study results. Consequently, we will objectively evaluate the efficacy of NVB sparing surgery by employing the validated PACE questionnaire (33).

Assessment of NVB sparing through recorded videos:

Robotic surgery provides video documentation of the entire procedure only of the abdominal/pelvic parts of the patients. There will be no recording of any of the exterior body part of the patients with identifiable features. These recordings will be used to evaluate and analyze the specific techniques employed in NVB-sparing RARP. The videos will be obtained from the laparoscopic stack in the operating theatres (SDC3 by Stryker) already in place at UCLH theatres. Data security handling is outlined in Section 11.

The assessment will be carried out by at least two independent high-volume radical prostatectomy surgeons, for each annotated video to evaluate interobserver variability. The external assessors will be blinded to the patient, operating surgeon and the patient outcomes.

For the assessment, the surgeons will use a standardized framework to annotate the videos, employing key performance indicators aligned with the domains of the PACE tool, which will be modified to suit NVB assessment. Each NVB (e.g., two assessments for patients undergoing bilateral NVB sparing) will be evaluated using a Likert scale for each domain.

Relevant data points, such as the time taken for specific tasks, error rates, and adherence to the surgical protocol, will be manually extracted from the annotated videos.

3.5 Assessment of functional outcomes:

Patient reported outcomes of EF and urinary continence:

Evaluation of outcomes will be carried out using validated questionnaires. EF will be assessed using an ED screening tool, IIEF-EFD and EPIC-26. Urinary continence will be assessed using the EPIC-26 continence domain.

Participants will receive the questionnaires prior to surgery (baseline), week 6, month 6, 12 and 24. These time points correspond to the normal appointment schedules provided to patients under the post-RARP penile rehabilitation.

Participants will fill in the form on paper or electronically and this will be transferred to the database by the research clinical fellow. Data protection measures are outlined in section 11.

We will used RedCap platform to offer patients a chance to complete the questionnaires through an electronic platform either via email or smartphone.

3.6 Controlling surgical confounders:

3.6.1 Sources of confounders:

The confounders of EF recovery are categorized into three categories: pre-surgical, surgical, and post-surgical. Comorbidities and baseline erectile functions are pre-surgical confounders. The quality of bilateral NVB sparing and intraoperative surgical complications are surgical confounders. The patient's overall well-being, post-surgical complications, and penile rehabilitation are all post-surgical concerns. Further to these patients can develop metabolic conditions (during their follow-up) contributing or exacerbating their ED.

3.6.2 Management of confounders:

To control the pre-surgical confounders the study is focusing on men with no pre-existing ED and no established vascular disease that increase the likelihood of ED (IHD, PVD, CVD)

The surgical confounders will be adjusted for by limiting the surgeons in the study and measuring the quality of the NVB sparing and intraoperative complications.
The post-surgical confounders will be balanced by administering a standardized, proven post-surgical penile rehabilitation protocol that is used by UCLH Urology. The protocol is provided is described in 1.2.5.

The post-surgical complications will be captured during follow-ups and the overall well-being will be captured through the validated tools administered. Appropriate statistical tests will be applied to adjust for these confounders. Patients who have ED will be investigated with routine blood tests to screen for metabolic causes of ED and will be accounted for in ad-hoc data analysis.

Further details of statistical analysis and methods employed to adjust for confounders are provided in the data analysis section.

3.7 Assessment of the pelvic vasculature with a postoperative an MR angiogram

By obtaining an MR angiogram with an arterial phase after the surgery, we will be able to confirm whether there is blood flow in the accessory pudendal arteries after surgery. This additional MRI at least 3 months after surgery will be only offered to patients who have an accessory pudendal artery on their preoperative mpMRI. This will be useful to assess whether the APA patency after surgery has an effect on EF outcomes. If there is an incidental finding on this MRI relating recurrence, then the parent team and the CI will be notified promptly. This will lead to further appropriate action.

We will follow an established and validated protocol for MRI angiography on month 3 (described in Appendix)

3.8 Penile doppler US (optional): Objective assessment of EF using erectile haemodynamics.

Penile Doppler ultrasound (PDUS) is a well-established diagnostic tool for ED in specialist clinical practice. As an optional part to the study, we will offer patients an opportunity to assess their erectile haemodynamics prior to surgery through a PDUS. The APA presence, features or absence will be known through review of their preoperative mpMRI. With that knowledge, the optional PDUS before surgery will outline the effect of APA on the haemodynamics in healthy men with prostate cancer.

Patients who will not respond to PDE5i after surgery will be offered with a PDUS to evaluate the flow of penile arterial blood and to provide objective evidence that the underlying cause of ED is arterial.

This will be an optional part to the study and will be offered at 6 months or earlier if patients wish to have ICI to treat their ED. This is the accepted standard of care for the evaluation of post-RARP ED that is not responding to medical treatment.

The standard penile doppler US protocol will be followed for patients who opt for this assessment. Details of the protocol are provided in appendix.

4 STUDY SCHEDULE

Study participants will adhere to the existing NHS pre-surgical, surgical, and post-surgical appointment schedule. Additional visits may be required for other components of the study which are the optional PDUS and postoperative MRI. Data collection will primarily occur during these standard interaction points.

Existing UCLH NHS PCa pathway:

Andrology follow-up to initiate penile rehabilitation after radical prostatectomy occurs prior to surgery with a telephone consultation and every 3 months after surgery. This is to provide information and set expectation prior to surgery and treat ED appropriately after surgery.

Screening will be carried out by reviewing:

a. Theatre lists for patients undergoing RARP
b. MDT lists
c. Pre surgical imaging-based planning meeting to determine eligibility for NVB sparing

Eligible participants will be approached and invited to the study during the pre-surgical andrology telephone appointment, which is standard of care at UCLH. The pre-surgical multidisciplinary team consultations conducted by consultant robotic PCa surgeons is a second point where participants can be approached. Potential participants who express an interest will be approached by the study research fellow to provide patient information sheet (PIS).

Recruitment logbook: A logbook will be maintained to track the number of patients who were designated as eligible, the number of who were approached, and the number of patients who consented to participate.

Recruitment: Patients, following time to review of PIS, who agree to participate will be provided with the opportunity to ask questions.

Robot assisted radical prostatectomy:

a. All surgeries are recorded as standard of care at UCLH.
b. To limit confounders, patients will be operated on by ZT, GS, BN and AS.
c. Video recordings of the RARP of recruited patients will be retrieved and stored on NHS hard drives

Follow-up with andrology is standard of care at 6 weeks, 6, 12 and 24 months. Participants will be reviewed at these points, and it will be ensured that functional questionnaires are completed. Patients will be provided with the choice of having their andrology appointments through telephone or face to face. Questionnaires will either be completed on paper or electronically through RedCap platform.

Blood tests: The metabolic assessment of ED includes testosterone, HbA1c and lipid profile biochemical profile. As part of routine post-surgical PCa follow-up all patients have a PSA tests done

at 2 to 3 months and either 1 or 3 more until month 12 depending on cancer features. We will use these time points to obtain the blood samples required for assessment of ED. Hence, additional hospital visits will be avoided. These blood samples that will be requested are standard part of assessment of ED therefore not leading to additional NHS costs. If the metabolic ED blood panel is normal, this will not be repeated again. Any abnormalities in these will be communicated to the patient and their general practitioner and where necessary, treatment will be recommended i.e. if patients have a new diagnosis of diabetes, the patient and their general practitioner will be informed to repeat the test and start treatment if necessary. These will then be retrospectively recorded by the research team. No samples will be obtained or stored as part of this research.

Postoperative MRI: For patients that undergoing bilateral NVB sparing RARP, with an APA identified on their preoperative mpMRI, an additional MRI will be offered at least 3 months after surgery to assess whether the accessory artery was preserved or sacrificed.

Penile doppler US: For patients opting to undergo a PDUS before and after surgery, an additional hospital visit may be required prior to surgery to perform the preoperative PDUS. Postoperatively, if patients do not respond to oral medication treatment for ED, they will be offered a PDUS during the same visit as their tutorial for intracavernosal injection (ICI) therapy, minimizing the need for additional hospital visits.

This tutorial, conducted in the clinic, ensures patients are proficient in self-administering alprostadil or Invicorp to achieve an erection. This approach aligns with the current standard of care for patients unresponsive to oral medications. During the clinic session, a penile Doppler US will be performed in conjunction with ICI self-administration to assess erectile haemodynamics comprehensively.

Additional visits:
Patients who have an APA identified on their preoperative mpMRI that are undergoing a bilateral NVB sparing RARP will be offered an additional MRI angiogram at 3 months to assess the patency of the accessory artery. All other aspects of their care will be the same including the preoperative andrology consultation, recording of their intracorporeal surgery as well as post operative care.

End of study
The end of the study is defined as the date of the final 12-month follow-up visit for the last recruited participant. Recruitment will stop once between 20 and 40 patients have been enrolled, and all participants will be followed for 12 months after surgery.

Table 1: showing Study specific schedule as well as standard clinic schedule

	Study specific schedules	Standard clinical schedule	Study specific assessments	Routine clinical assessments
Preoperative mpMRI prostate		X		
Prostate Biopsy		X		
Multidisciplinary meeting		X		
Clinic appointment to discuss treatment options		X		

Clinic appointment for patient decision: for surgery		X		
Radiology preoperative MRI meeting: for NVB surgery, identify APA	X (identify APA~)	X		
Eligibility assessment by study team	X~			
Preoperative andrology telephone clinic		X	IIEF-EFD, EPIC-26	IIEF-EFD, EPIC-26
Consent for research	X			
Pre-assessment for surgery		X		Routine bloods and assessments.
Optional: Penile doppler before)			X	
Surgery: RARP		X	Consent for research	
First surgical follow up appointment 6 weeks		X		
Andrology appointment at 6 weeks, 6, 12 and 24 months.		X	IIEF-EFD, EPIC-26	
Routine cancer and surgical follow up at 3 months		X		All patients: PSA, Patients with ED: Testosterone, HbA1c, lipid profile

~ This is done by the study team and does not constitute and additional visit by the patients.

5. ELIGIBILITY CRITERIA

Eligibility criteria	
Inclusion criteria	• Men diagnosed with cT2-T3a N0 M0 PCa aged between 18 and 79 from all ethnic backgrounds. • Patients who underwent a prostate mpMRI before prostate biopsy. • Medically fit to undergo RARP. • Diagnostic quality prostate biopsies concordant with a diagnostic quality prostate mpMRI adequate to provide a surgical plan.

	• Scheduled for RARP with a recommendation of BL NVB spare based on multidisciplinary meetings informed by mpMRI, biopsy result and clinical factors. • Sexually active men with no to mild ED at baseline based on IIEF-EFD (>=24). • Preference to preserve erectile function for sexual intercourse. • Ability to read English sufficiently to understand PIS and able to give informed consent.
Exclusion criteria	• Established moderate/ severe ED (IIEF-EFD <24) • Patients who received neo-adjuvant androgen deprivation therapy. • Patients with previous surgery for benign prostatic enlargement • Patients who received previous treatment for prostate cancer: External beam radiotherapy, brachytherapy, focal therapy, chemotherapy. • Previous pelvic or penile fracture • Previous surgery for ED • Poor quality prostate mpMRI or biparametric MRI (no contrast) • Established vascular disease (ischaemic heart disease, cerebrovascular disease, peripheral vascular disease)

5 RECRUITMENT

1. Screening for eligible will be carried out by looking through
    a. Theatre lists for patients undergoing RARP
    b. MDT lists
    c. MRI planning meeting where NVB sparing plan is made
2. Enrolment for eligible patients at the pre-operative andrology telephone appointment
    a. This is standard of care at UCLH.
    b. Eligible patients will be presented with the research and recruited as per detailed below
    c. PIS and consent forms
    d. Baseline questionnaires

Currently, all patients that are scheduled for RARP at UCLH receive phone call from the andrology department clinical team to outline the expectation of EF changes and recovery after surgery. This is currently standard operative procedure at UCLH and is routine provide patient centred andrology care. During this telephone consultation, all eligible patients will be given information about the research. If they are interested to learn more about this, the patient information sheet as well as research consent form will be emailed or posted to the patient. This will be at least 24 hours prior to their surgery. A dedicated member of the clinical research team will approach them again during their hospital admission and provide them with the chance to ask any questions. If patients wish to take part in the study, the consent form will be collected from the patient by the andrology research team during their hospital admission.

6 CONSENT

Potential participants will be approached via telephone during their planned preoperative andrology telephone appointment prior to their surgery date. They will receive an electronic PIS sent via NHS email or post. They will have at least 24 hours to read the study, reflect on the information provided and have the opportunity to ask questions. During their hospital hospitalisation, a selected member of the clinical team will approach them again and provide them with the opportunity to ask any questions and sign the consent form for those agreeing to enrol in the study.

Patients may express interest by phone, but formal consent will only be obtained in writing after discussion with the research team.. The electronic consent platform will be developed within the RedCAP service hosted behind the UCL Data Safe Haven, which conforms to NHS Data Security & Protection Toolkit, General Data Protection Regulation, and ISO 27001 Information Security. Patients cannot sign consent until a face-to-face (or secure e-consent) discussion with the research team.

A copy of the consent form will be given to the patient, a copy uploaded to the electronic health records of the patient and the original will be stored in the ISF. All members of the team consenting patients will be suitably qualified, experienced, and will have been delegated this duty by the CI/ PI on the Staff Signature and Delegation of Tasks.

When the participant receives the participant information sheet (PIS), it will be recorded in the patient's medical notes (or electronic health record). The PIS and consent form will be reviewed and updated, if necessary, throughout the study (e.g. where new safety information becomes available) and participants will be re-consented as appropriate.

At every review at regular intervals, patients will be given the opportunity to withdraw from the research study.

Electronic Consenting

The electronic consent platform will be developed within the RedCAP service hosted behind the UCL Data Safe Haven, which conforms to NHS Data Security & Protection Toolkit, General Data Protection Regulation, and ISO 27001 Information Security.

7 DATA ANALYSIS

Univariate and multivariate regression models looking at the imaging parameters values, video quality ratings, baseline EF scores to predict EF scores at 12 months. Correlation coefficients between the imaging parameters values, video quality ratings, baseline EF scores to predict EF scores at 12 months intervals. Interobserver discordance will be arbitrated by a third independent reviewer. We will utilise the data management software R to carry out the statistical analysis.

To address missing data in validated erection function questionnaires, we will use Multiple Imputation (MI), a widely accepted method that handles missing data under the Missing at Random (MAR) assumption. MI imputes missing values multiple times to create several complete datasets, which are analysed separately, and results are pooled using Rubin’s rules to incorporate imputation uncertainty. This approach retains all participants, preserving statistical power and minimizing bias. We will use the mice package in R to perform MI, incorporating clinically relevant variables such as baseline characteristics and prior questionnaire responses, with diagnostic checks ensuring plausible imputations. This method is robust, scientifically sound, and commonly used in observational studies.

8 PATIENT AND PUBLIC INVOLVEMENT (PPI)

We have identified three patients who have had NVB sparing surgery at UCLH and discussed the study with them sharing the lay summary of the research, study design and PIS and consent forms. We also discussed with them their perception of the electronic consenting as well as electronic data collection. They confirmed the suitability and feasibility of the study from a patient perspective.

9 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office and deemed sufficient to cover the requirements of the study. NHS costs will be supported via UCLH and/or the Local Clinical Research Network.

Abdullah research fellow- his time has been fully funded and costed. The penile doppler US will be carried out by Abdullah who is trained to carry out penile doppler US.

Funding has been acquired for the postoperative MRI. The costs will only be required for carrying out the MRI as the reporting will be done free of charge by the uro-radiologist which are part of the research team.

10 DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is data-protection@ucl.ac.uk. The data processors are [Abdullah Al-Mitwalli, Zafer Tandogdu]. The study will be collecting the following personal data:

-Patient data: Basic patient information will be kept including hospital numbers, names and date of births. This will be the key and will be kept in a separate file. All other data collected will (non-identifiable information) will be in pseudonymised fashion in a separate sheet. All files will be password protected. MRI markers will be kept as part of the pseudonymised data sheet. The questionnaires will be scanned and uploaded onto the individual patient electronic records. Consent forms are discussed in section 6.

A study key including a list of participants (identified by their hospital number) along with the corresponding trial personalised identification number will be stored in a file on a secure computer in Westmoreland Street Hospital, UCLH NHS Trust, under one login. This is in a locked office. This file will be password protected. Any paper questionnaires and consent forms will be stored in the locked office at UCLH. The EF questionnaires will be scanned and uploaded onto the individual patient electronic records. When the consent form is complete, 1 will stay with the participant; 1 for researcher site file; 1 to be kept in medical notes electronically.

-The video recordings: This will be done through the standard operating stack and require no additional steps to changes to standard care. Currently, the procedures are routinely recorded in the operating room for training purposes and to evaluate where improvements could be made. We do not anticipate that there will be any new material ethical issues associated with the recording

system. The videos will be entirely anonymised so no patient identifiable information will be available on the actual video. In the file name, it will have a study number. The study number will be the pseudonymised. The key will only be kept at a UCLH NHS computer. All files will be password protected. The videos will be uploaded to the password protected file on NHS one drive. They will have no identifiable information. When they are edited, they will be presented to other NHS surgeons who perform RARP through the NHS drive. The surgeons will rate the quality of the videos but will view no identifiable information and will not be able to download the videos.

-The postoperative MRI will be stored on university drive and may be used in other studies.

PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL.

The study was deemed to require regulatory approval from the following bodies (NHS REC Favourable Opinion and HRA Approval). **Before any site can enrol patients into the study,** the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

11 ASSESSMENT AND MANAGEMENT OF RISK

-Data management risks are discussed in section 10.

-Video recordings: This will be done through the standard operating stack and require no additional steps to changes to standard care. Currently, the procedures are routinely recorded in the operating room for training purposes and to evaluate where improvements could be made. The management of the video data file is discussed in section 10.

-Hospital visits: for participating patients, an additional MR angiogram will be obtained postoperatively for study participants which will require an additional visit to the hospital. The remaining appointments will align with the standard andrology follow-up after radical prostatectomy.

-Penile dopplers (OPTIONAL) A penile doppler US will be offered to patients before and after surgery to assess the erectile machinery for study participants. This will be particularly useful for patients that fail to achieve satisfactory erections with medical treatment after surgery. A large proportion of patients that fail medical treatment and wish to escalate their erectogenic treatment will require injection treatment to the side of the penis. During the tutorial for this therapy, we will carry out a penile doppler ultrasound to assess their EF objectively and asses the blood flow to the penis.

The use of penile dopplers will require injection into the penis with Alprostadil or Invicorp (phenotmaline and aviptadil) which are an erection inducing medication. Both of these injections are commonly used to treat ED especially in men with radical prostatectomy so a significant proportion of men will have an injection after surgery in non-research setting. The commonly used trade name for alprostadil is VIRIDAL DUO or CAVERJECT. This carries a small risk of a prolonged painful erection which is a urological emergency if lasts more than 4 hours (risk of 1% with alprostadil or 0.3% with invicorp). Patients will be consented again and will have the right to withdraw their consent to have this investigation. Patients will be monitored for at least 2 hour after their ultrasound to ensure their erection is reducing before they go home. If they do develop a prolonged erection, they will be offered treatment by the research andrology team promptly prior to developing a priapism. This will ensure that no patient will develop priapism after these penile doppler US. Careful safety netting will be provided for patients and advice to seek urgent urological care if they develop a prolonged painful erection.

11.1 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor via UCL: research-incidents@ucl.ac.uk or UCL REDCAP incident reporting form) and host sites via their Trust reporting systems, and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

Definitions

Term	**Definition**
Adverse Event (AE)	Any untoward medical occurrence in a patient or trial participant, which does not necessarily have a causal relationship with the intervention involved.
Serious Adverse Event (SAE).	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation**,

	• results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect. • Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences
* A life- threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an in-patient admission, regardless of length of stay. Hospitalisation for pre-existing conditions, including elective procedures do not constitute an SAE.	

3.1. Assessments of Adverse Events

Each adverse event (AEs) will be assessed for severity, causality, seriousness and expectedness from consent to 90 days post op as it unlikely any SAEs past this point will be related to surgery. Adverse event assessment will be carried out using the patient electronic clinical records. This will reduce site reporting workload. Trial follow up should continue according to schedule once the SAE is resolved, if applicable.

3.1.1. Severity

Category	**Definition**
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further intervention; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further intervention, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

3.1.2. Causality

The assessment of relationship of an adverse event to this/these additional safety issue(s) will also be carried out as part of the study.

The differentiated causality assessments will be captured in the trial specific CRF SAE form.

The following categories will be used to define the causality of the adverse event:

Category	**Definition**
Related	A causal relationship between the intervention and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.
Not related	There is no reasonable possibility of a causal relationship between the intervention and an adverse event.
Not Assessable	Unable to assess on information available.

3.1.3. Expectedness

All SAEs assigned by the Investigator or delegate as suspected to be related to the intervention will be assessed for expectedness against the list defined in this protocol.

Category	Definition
Expected	An adverse event which is consistent with the information about the intervention **clearly defined in this protocol.**
Unexpected	An adverse event which is not consistent with the information about the intervention **or clearly defined in this protocol.**

The following are expected adverse events following a our research study

11.2 Personal Data Breaches

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer data-protection@ucl.ac.uk , and to the Sponsor via the UCL JRO research incident reporting form (as per form and guidance: https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply). Sites will additionally follow their Trust incident reporting mechanisms, and will document this within their TMF/ISFs.

11.3 Adverse Events and Serious Adverse Events Sponsor Reporting Requirements (if applicable)

Adverse events are any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. These do not require reporting to the Sponsor, but the severity, causality and expectedness will be recorded in the participant's medical records, CRF and AE log, with a description of clinical symptoms and the event, including dates as appropriate.

SAEs (any event that results in death, is life-threatening, requires hospitalisation or prolongation of existing inpatient hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect) that have been determined to be **unrelated** to the research intervention by the CI/PI do not require reporting to the Sponsor, but will be recorded in the participant's medical records, CRF and site file. Additionally, **expected** SAEs that are likely to occur on a regular basis and offer no further new information to the safety profile, or are related to the disease area of the participants, do not require reporting to the Sponsor, but must be recorded as previously stipulated. Sponsors will however be notified where the frequency and severity of unrelated SAEs are unusual; research sites will report as per Sponsor reporting requirements.

In some instances, **unexpected and related SAEs** may occur in observational research [for example, Clausterphobia during MRI scans, allergic reaction with contrast agent during MRI or towards medications during scans]. All reportable SAEs will be recorded in the medical records and CRF, and reported to the Sponsor via the JRO REDCAP research incident reporting form or research-incidents@ucl.ac.uk, within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the Sponsor as soon as possible.

All adverse events will be recorded in the medical records in the first instance. All related adverse events will be recorded in the CRF until 90 days after surgery.

All related adverse events will also be recorded on the non-CTIMP Adverse Event (AE) log, and stored in the site files.

All serious adverse events related to the intervention will be recorded in the medical records and the CRF, and the sponsor's SAE log. The AE and SAE logs will be stored in the TMF Investigator Site File and may be subject to Sponsor monitoring and auditing.

All SAEs (except those specified in the protocol as not requiring reporting to the Sponsor) will be reported to the Sponsor within 24 hours of becoming aware. The CI/PI or designated individual will complete the Sponsor's online Research Incident Reporting Form (https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo) within 24 hours of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the Sponsor as soon as possible.

In the first instance, research participant complaints (patients or health volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy. For participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures were undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

11.4 Incidental Findings in Research

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

11.5 Protocol deviations and notification of protocol violations

The Sponsor will be notified immediately of any protocol violations during the study conduct phase by completion of the online JRO Research Incident Reporting Form: https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo. All protocol violations must be recorded on the Protocol Violation Log and filed in the site file. Protocol deviations will be reported on the Protocol Deviation Log and filed in the site file.

11.6 Reporting incidents involving a medical device(s)

N/A

11.7 NHS Serious Incidents and near misses

A serious incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

11.8 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor [via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

12 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

13 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files

14 INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property rights deriving or arising from the material or any derivations of the material provided to UCL by the participating site shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, effectively assigns all such intellectual property rights ("IPR") to UCLand discloses all such know-how to UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating sites from using its own know how or clinical data gained during the performance of the study, as its own risk, in the furtherance of its normal activities or providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information of the infringement of an intellectual property rights of UCL or their funder. This section does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the study.

15 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

Hospitals selected to participate in this clinical study shall provide clinical negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary shall be provided to University College London upon request.

Additionally, UCL does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity.

16 ARCHIVING

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at WMS for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL, in accordance with the UCL Retentions Schedule and Policy. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

NB: UCL do not archive student projects and therefore, the length of storage is not subject to the standard Sponsor requirements.

17 PUBLICATION AND DISSEMINATION

Results of scientific interest from the study and any parallel translational work will be submitted for consideration for presentation to professional and scientific meetings, and publications in peer reviewed professional and scientific literature. They may also be included in theses and dissertations.

Any submissions are to have authorisation from the chief investigator and co-investigators upon review by the chief investigator. Authorship will be determined on a per paper basis. The chief investigator will have final say if agreement cannot be reached.

Resulting publications and/or abstracts will be emailed to the JRO.

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19 APPENDICES

19.1 Associated Documents

Document Name	Document Version	Document Date
PIS		
Consent form		
Logbook		
GP LETTER start		
GP LETTER update		
GP LETTER end		

Protocol for MR Angiography

1. Patient Preparation- as standard for patients at UCLH undergoing multi-parametric MRI for diagnostic PCa purposes with regards to position, fasting, bladder status and reimaging checklist
2. Imaging Equipment and specification: As available at UCLH
3. Contrast Agent
   -Gadolinium-based contrast agent at the standard dose normally given to patients undergoing a preoperative mpMRI
   -Ensure standard injection rate (2–3 mL/s) via an injector.
   -Timing of contrast injection: The goal is to capture both arterial and venous phases.
   -Timing protocols:
   -Use a bolus tracking technique or test-bolus method to time the arterial phase.
   -Delayed imaging for venous phase (roughly 60–90 seconds after injection).
4. Imaging Sequences
   -Initial Survey Sequence: Perform a coronal and axial T2-weighted sequence as an overview to visualize pelvic structures and position the following sequences.
   -Key Imaging Sequences:
   A. Dynamic Contrast-enhanced (DCE) Imaging
   B. Dynamic sequence: For capturing the different phases of contrast passage.
   -Acquire at intervals of 3–5 seconds during and after contrast administration.
5. Coverage and Field of View.
   -Anatomical coverage: From the iliac bifurcation down to the penile base to ensure the -visualization of major pelvic arteries, including internal iliac and its branches (inferior vesical, internal pudendal, and accessory pudendal arteries).

Protocol for Penile Doppler Ultrasonography (PDUS)

1.Obtain verbal and written informed consent.
2.Preparation:
-Ensure private examination room

-Position patient supine
-Apply ultrasound gel to penis
3.Pre-injection examination:
-Perform gray-scale imaging
-Record baseline measurements of cavernosal arteries
4.Intracavernosal Injection:
-Administer ICI of Alprostadil or Invicorp
-Apply gentle pressure to injection site
5.Post-injection examination:
-Await assessment of rigidity
-Perform color Doppler imaging of cavernosal arteries
-Measure and record peak systolic velocity (PSV) and end-diastolic velocity (EDV)
-Calculate resistive index (RI)
6.Interpretation:
Arterial insufficiency: PSV <25 cm/s
Venous leak: EDV >5 cm/s and RI <0.75
Normal: PSV >30 cm/s, EDV <5 cm/s, and RI >0.8
7.Post-procedure:
-Observe patient for 2 hours to ensure detumescence
-Provide instructions for potential side effects
8.Documentation:
-Prepare report with findings and diagnosis
-Archive relevant images and waveforms
PACE TOOL(33):

PACE - Prostatectomy Assessment and Competency Evaluation

DOMAINS*	1	2	3	4	5
Bladder Drop					
Identify and Dissect away from Umbilical Ligaments & Pubic Bone	• Injury to the Bladder/Pelvic Side Wall and/or adjacent Obturator Vessels/Nerve	2	• Entry into Peri-vesical Fat; or Bleeding Obscuring the Operative Field; or Inadequate Lateral Dissection and/or Curtain of Tissue left anteriorly	4	• Clean Dissection that respects all Surgical Planes with Minimal /no Bleeding and Preservation of Accessory Vessels if present
Preparation of the Prostate					
Defatting Prostate with Dorsal Venous Complex (DVC) Preservation	• DVC and/or Periprostatic Bleeding • Inadequate Defatting/Injury of Anterior Prostate-Vesical Junction • Untimely and/or Inadvertent Opening of Endopelvic Fascia • Bladder not released from Pelvic Side Wall	2	• Suboptimal Hemostasis • Inadequate Anterior Prostate-Vesical Exposure with Acceptable Bladder release from Pelvic Side Wall	4	• Adequate Prostate-Vesical Exposure with Minimal/no Bleeding • Appropriate and Planned Opening of Endopelvic Fascia • Bladder released from Pelvic Side Wall
Bladder Neck Dissection					
Dissection of the Bladder Neck from the Prostate	• Wrong Plane with Subsequent Entry into the Prostate and/or weak (thin) Posterior Bladder Neck • Injury or close proximity to the Ureteric Orifices or Trigone • Leaves Prostate Tissue on the Bladder	2	• Disproportionate Bladder Neck • Deviates from Prostate-Vesical Junction but returns to the Correct Plane	4	• Identifies and divides the Natural Groove which delineates the Prostate-Vesical Junction • Proportionate Bladder Neck with adequate thickness and without entry into the Prostate
Dissection of the Seminal vesicles (SV) and Posterior Anatomical Plane					
Dissection of Seminal Vesicles (SV)	• Unintentional Retained Portion of SV • Excessive Use of Cautery • Uncontrolled bleeding from vessels around SV	2	• Complete Removal of the SV despite Inadvertant Entry • Vessels Torn with subsequent Control of Bleeding	4	• Complete Atraumatic Removal of SV with Minimal Traction • Appropriate Use of Cautery
Development of Posterior Anatomical Plane	• Entry into the Base of the Prostate • Inappropriate use of Cautery • Rectal injury	2	• Initial Entry into Suboptimal Plane close to the Prostate or Rectum with subsequent Correction of the Anatomical Plane	4	• Anatomical Plane created down to the Posterior Urethra with Minimal Bleeding and Tearing of Tissue
Preservation of Neurovascular Bundle (NVB)					
Neurovascular Bundle (NVB) Preservation	• Entry into the Prostate • Inappropriate Use of Cautery • Damage to the Main Trunk of the NVB	2	• Excessive Traction on/around NVB • Poor Set up/Visualization of Operative Field • Excessive Bleeding • Inadequate Release of NVB at/ adjacent to Apex of the Prostate	4	• Balanced Hemostasis with Proper Dissection up to and beyond the Apex of Prostate and Urethra • Appropriate Use of Cautery
Apical Dissection					
Apical Dissection	• Entry into the Apex of Prostate with Remnants of Prostate Tissue left on the Urethra • Untimely Entry ino the DVC • Excessive Traction and injury/ shortening of the Urethra • Injury to the Lateral Apical NVB	2	• Unable to clearly separate Prostatic Apex from the Urethra • Inadequate Closure of the Dorsal Venous Sinuses with Persistent Bleeding • Uneven edges of the urethral incision	4	• Complete Control of Dorsal Venous Sinuses with Adequate Urethral Length and Preservation of the NVB
Urethro-Vesical anastomosis					
Needle Entry	• Needle Tip usually (>75%) enters Non-Perpendicular	2	• Needle Tip usually enters half the time Non-Perpendicular	4	• Needle Tip usually (>90%) enters Perpendicular
Needle Driving & Tissue Trauma	• Wrist Rotation seen <25% times with Tissue Trauma	2	• Wrist Rotation seen <50% times with Minimal Tissue Trauma	4	• Wrist Rotation almost always (>90%) seen with no Tissue Trauma
Urethro-Vesical Approximation	• Poor Approximation of Posterior Plate • Significant Leakage after Irrigation requiring Re-anastomosis	2	• <50% of Circumferential Approximation • Minor Leakage after Irrigation requiring Repair	4	• Well Approximated • Water Tight after Irrigation

* The presence of any single or multiple criteria within each anchor qualifies for that score.