The First Affiliated Hospital of Zhengzhou University Informed Consent Form:

Information Sheet

Study Title	A Prospective, Randomized Controlled Study Comparing the Integrated Posterior–Anterior–Lateral (PAL) Approach and the Posterior Approach in Robot-Assisted Radical Prostatectomy
Sponsor	Urology Ward 6
Protocol Number:	V2.0
Date:	May 10, 2024
Research Institution Name:	The First Affiliated Hospital of Zhengzhou University
Research Institution Address:	No. 1 Jianshe East Road, Erqi District, Zhengzhou City, Henan Province
Principal Investigator:	Xuepei Zhang
Contact Number:	13837110911
Patient Initials:	
Patient Screening Number:	

Subject Information

1. Study Background:

You are being invited to participate in a clinical study initiated by Ward 6 of the Department of Urology at The First Affiliated Hospital of Zhengzhou University and led by Principal Investigator Xuepei Zhang at this center. This is a randomized controlled study designed to investigate the perioperative outcomes, cancer control, and postoperative functional recovery of two different surgical approaches for robot-assisted radical prostatectomy. The study will last for one year. This study has been reviewed and approved for establishment by the Scientific Research Department of The First Affiliated Hospital of Zhengzhou University and has passed the review of the Hospital's Ethics Committee, which has approved its conduct.

This informed consent form provides you with information about this clinical study to help you decide whether to participate.

If you agree to participate in this study, please read the following instructions carefully...

Please read the following information carefully. If you have any questions, please direct them to the investigator in charge of this study.

2. Study Purpose:

Radical prostatectomy is the standard treatment for localized prostate cancer. Rassweiler et al. first reported robot-assisted radical prostatectomy (RARP) in 2001. Given the Da Vinci robot's high-definition three-dimensional imaging and flexible, stable robotic arms, it is particularly suited for performing more precise dissection and suturing in confined spaces. Consequently, RARP has rapidly gained popularity worldwide and has even replaced traditional laparoscopic and open surgery in some hospitals. Patel et al. proposed the "pentafecta" for radical prostatectomy: long-term cancer control, urinary continence preservation, erectile function preservation, absence of surgical complications, and negative surgical margins, which remains the goal pursued by urologists. To achieve better treatment outcomes, surgeons have conducted in-depth research on various RARP approaches, such as the anterior, posterior, lateral, and transvesical approaches. However, each RARP approach has its own advantages and disadvantages.

To maximize the benefits of each approach, based on our center's experience with over 1000 radical prostatectomies, we were the first in China to propose the combined approach RARP in 2022. This approach involves initially using the posterior approach to separate the vas deferens, seminal vesicles, and Denonvilliers' fascia, followed by the anterior approach to separate the retropubic space, and then the lateral approach to separate the bladder neck and preserve the neurovascular bundles (NVB) as much as possible. The PAL combined approach RARP already implemented at our center has shown significant results in achieving the "pentafecta": long-term cancer control, urinary continence preservation, erectile function

preservation, absence of surgical complications, and negative surgical margins. This study aims to compare the perioperative outcomes, pathological results, and early functional outcomes of the PAL combined approach RARP and the posterior approach (Retzius-sparing) RARP in the treatment of prostate cancer, to provide a better foundation for the application of the PAL combined approach RARP.

3. Inclusion and Exclusion Criteria:

This study plans to enroll no fewer than 30 patients per group.

(1) Inclusion Criteria:

Age ≥ 40 years and ≤ 80 years;

Diagnosis of prostate cancer confirmed by prostate biopsy;

Clinical T stage ≤ T3a;

Full understanding of the clinical trial protocol and provision of signed informed consent.

Any outpatient or inpatient volunteer patient who meets all the above criteria can be enrolled as a subject.

(2) Exclusion Criteria:

Pre-existing urinary incontinence;

Previous endoscopic prostate surgery;

Presence of severe underlying diseases rendering the patient unable to tolerate surgery or with a life expectancy of < 5 years;

Presence of metastatic disease or suspected lymph node involvement at diagnosis;

Patients deemed by the investigator as unsuitable for participation in this clinical trial.

Any patient meeting any of the above criteria cannot be enrolled as a subject.

(3) Discontinuation (Withdrawal) Criteria:

This refers to all patients who have signed the informed consent form, passed screening, and entered the trial but subsequently withdraw from the clinical trial.

Common reason: The patient requests to stop the trial.

4. Study Process and Methods:

If you agree to participate in this study, we will assign a unique number to each subject and establish a study file. During the study, you may be assigned to either the PAL combined approach RARP group or the posterior approach (Retzius-sparing) RARP group. We will communicate with you or your family in detail, explaining the relevant aspects of the study, and we ask you to provide information related to your condition, including the onset process, family history, previous medical consultations, and results of any previous examinations. You will also be asked to complete questionnaires designed for this study.

5. Potential Benefits of Participation:

Studying your perioperative outcomes, pathological results, and early functional outcomes will help in diagnosing the condition, providing necessary treatment recommendations for you, or offering valuable information for disease research.

Researching your information will provide necessary suggestions for your treatment or beneficial information for disease research.

Enrolled patients may achieve better postoperative urinary continence outcomes without increased surgical risk. According to our center's retrospective study results [1], compared with the conventional approach, the PAL combined approach RARP for treating PCa is equally safe and effective and shows better early postoperative urinary continence. Previous literature on the posterior approach RARP versus conventional approaches also indicates some advantages for urinary continence recovery. However, this is the first study comparing these two surgical methods in terms of operative time, intraoperative blood loss, urinary continence, etc. Individual patient conditions vary, and postoperative recovery may differ for each person; there is a possibility of not benefiting compared to the conventional procedure.

[1] Li Zhenhao, Zhu Zhaowei, Zhao Pin, et al. A propensity score-matched cohort study comparing the clinical outcomes of two different surgical approaches in

robot-assisted radical prostatectomy [J]. Journal of Modern Urology, 2024, 29(07): 602-606+611.

6. Research Risks and Discomforts:

All your information will be kept confidential. Your surgery will be performed by professionals such as surgeons. The differing parts of the two surgical groups are only portions of the complete surgical procedure, and the research will not impose additional risks or complications on your surgery. According to our center's retrospective study results, compared with the conventional approach, the PAL combined approach RARP for treating PCa is equally safe and effective and shows better early postoperative urinary continence. Previous literature also indicates advantages for urinary continence recovery with the posterior approach. However, as this is the first study comparing these two surgical methods in aspects like operative time, intraoperative blood loss, and urinary continence, and given that individual patient conditions vary, postoperative recovery may differ. Both surgical approaches still carry risks of intraoperative and postoperative complications (such as bleeding, infection, etc.) and slower recovery of urinary continence. There is a possibility of not benefiting or even experiencing slower recovery compared to the conventional procedure.

All your information will be kept confidential and will not cause unnecessary impacts on you and your family.

Communicating and conversing with us might cause some psychological discomfort for you, but we strictly guarantee the confidentiality of this information.

7. Alternative Treatment Options:

You are informed that besides participating in this study, other available treatment options include anterior approach RARP, lateral approach RARP, and laparoscopic radical prostatectomy.

8. Privacy Protection:

If you decide to participate in this study, your participation and personal data within the study will be kept confidential. Your blood samples will be identified by a study code number, not your name. The principal investigator and other research staff will use your medical information to conduct the research. This information may include your name, address, phone number, medical history, and data obtained during your study visits. Information that can identify you will not be disclosed to anyone outside the research team unless you give permission. All research staff and the study sponsor are required to keep your identity confidential. Your records will be stored in locked file cabinets, accessible only to authorized research personnel. To ensure the study is conducted properly, representatives of government regulatory agencies or the ethics review board may inspect the study site and review your personal information as required by regulations. When the results of this research are published, no information that could personally identify you will be disclosed.

When the results of this study are published, commitments regarding confidentiality will also be made.

9. Costs and Compensation:

This research project involves the conventional robot-assisted radical prostatectomy (RARP), which is a mature technique. The intervention in this study constitutes part of the surgical procedure, employs mature techniques, and is not expected to increase perioperative risk for patients. Common complications after RARP include postoperative urinary incontinence, urinary leakage, and short-term urinary retention, which usually resolve spontaneously.

During your participation, the doctors will make every effort to prevent and treat any harm that may result from this study. If injury related to the research occurs, and it is confirmed by a medical expert committee to be related to this study, the sponsor will provide necessary medical treatment for the injury and/or appropriate compensation in accordance with relevant regulations.

10. Voluntary Withdrawal:

As a subject, you have the right to inquire about information related to this study and its progress at any time. You can voluntarily decide (to continue) to participate or not (to continue) to participate. After participation, regardless of whether any harm occurs or its severity, you can choose to notify the researcher at any time to withdraw from the study. Data collected after your withdrawal will not be included in the research results. Your medical treatment and rights will not be affected in any way because of this. If continuing the study causes you significant harm, the investigator will also discontinue the study.

If you have questions related to the study content, please contact the research doctor at the following number: 13243131252. If you have questions related to your rights and interests, you may contact the Ethics Committee using the contact information provided in the footer of this informed consent form.

The First Affiliated Hospital of Zhengzhou University

Informed Consent Form - Consent Signature Page

I have carefully read this informed consent form. I have had the opportunity to ask questions, and all my questions have been answered. I understand that participation in this trial is voluntary. I may choose not to participate in this trial, or I may withdraw at any time after notifying the investigator without facing discrimination or retaliation, and my medical treatment and rights will not be affected. If I require other diagnoses/treatments, if I do not comply with the trial plan, or if there are other justified reasons, the investigator may terminate my continued participation in this clinical trial.

I voluntarily agree to participate in this clinical trial and will receive a copy of this signed informed consent form.

Please copy the following statement:

"**I have read and understood this clinical trial, and I voluntarily participate in this clinical trial.**"。

Subject Name:	_____
Subject Signature:	_____
Subject ID Number:	_____
Contact Phone Number:	_____
Date:	_____
Guardian's Name:	_____
Guardian's Signature:	_____
Guardian's ID:	_____
Relationship to Subject:	_____
Contact Phone Number:	_____
Date:	_____

（*When the subject or their legal guardian is unable to read, the following alternative procedure shall be added or substituted:*）

Impartial Witness Name:	_____
Impartial Witness ID Number:	_____
Impartial Witness Name:	_____
Contact Phone Number:	_____
Date:	_____

I have accurately informed the subject of the contents of the informed consent form and have answered all questions raised by the subject. The subject has voluntarily agreed to participate in this clinical trial and has been provided with a copy of the signed informed consent form.

Research Physician's Name:	_____
Research Physician's Signature:	_____
Contact Phone Number:	_____
Date:	_____