PROTOCOL

Observing the migration rates and patient-reported stent-related outcomes of Single J Ureteric Stents following Ureteroscopy

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Author/s:
Joseph Ischia, Anthony Ta, Varun Buhariwalla

Sponsor/s:
Nil

CONFIDENTIAL

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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STUDY SYNOPSIS

(please provide a brief information)

Title:	Observing the migration rates and patient-reported stent-related outcomes of Single J Ureteric Stents following Ureteroscopy
Short Title:	Single J Ureteric Stents following Ureteroscopy
Design:	Interventional, non-randomised single-centre prospective cohort study
Study Centres:	Austin Health
Hospital:	Austin Hospital; Heidelberg Repatriation Hospital
Study Question:	Is a Single-J ureteric stent with no distal loop in the bladder a valid, safe and beneficial alternative to Double-J stents following Ureteroscopy?
Study Objectives:	Understand how well SJS are tolerated by patients in comparison to standard DJS and if they are safe in their rates of migration.
Primary Objectives:	Measure stent migration rates in patients with Single-J Ureteric Stents post Urological Surgeries
Secondary Objectives	1. Patient-reported postoperative stent-related symptom scores on a validated Questionnaire (USDT) 2. Stent-related complications (infection, encrustation, hematuria)
Inclusion Criteria:	• Age ≥18 years. • Undergoing elective URS or Pyeloscopy and stent exchange for ureteric stone disease. • Already pre-stented with a Double-J ureteric stent prior to URS. • Able and willing to provide informed consent. • Sufficient English proficiency to complete symptom questionnaires (USDT).
Exclusion Criteria:	• Single kidney or bilateral ureteric disease. • History of ureteric strictures or prior ureteric reconstruction. • Pregnancy or breastfeeding. • Active urinary tract infection at time of URS. • Immunocompromised state (e.g., ongoing chemotherapy, high-dose steroids). • Any contraindication to ureteric stenting or flexible cystoscopy.

	• Patients unwilling or unable to comply with follow-up procedures. • Complex surgical case ○ Very large ureteric stone (>10mm), impacted stone, stone in intramural ureter, difficult stent, significant bleeding after stenting
Number of Planned Subjects:	40
Investigational product:	Modified Bander Ureteral Diversion Stent
Safety considerations:	Possible increased risk of stent migration due to absence of distal loop
Statistical Methods:	• Comparison of USDT scores with DJS and SJS within participants using the paired t-test for normally distributed data. • If normality assumptions are violated, the Wilcoxon signed-rank test will be applied. • Descriptive Statistics for demographics
Subgroups:	
PhD or Masters student using data towards their degree:	☐ Yes, please contact the Office for Research to discuss whether an agreement is needed ☒ No

1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
SJS	Single-J Stents
DJS	Double-J Stents
URS	Ureteroscopy
USDT	Ureteric Stent Discomfort Test

2. STUDY SITES

a. STUDY LOCATION/S

Site	Address	Contact Person	Phone	Email
Austin Hospital	145 Studley Rd, Heidelberg VIC 3084	Varun Buhariwalla	0424628495	Varun.buhariwalla@austin.org.au
Heidelberg Repatriation Hospital	300 Waterdale Rd, Ivanhoe VIC 3079	Varun Buhariwalla	0424628495	Varun.buhariwalla@austin.org.au

3. Introduction/Background Information

a. Lay Summary

This study aims to investigate a new approach to ureteric stenting following ureteroscopic stone surgery. Normally, after such procedures, patients have a Double-J (DJS) stent inserted, which loops at both ends inside the body. These stents are effective but often cause discomfort, bladder irritation, and other urinary symptoms.

In this study, we aim to modify a standard Bander Ureteral stent, normally used in Cystectomy surgeries, by shortening its straight lower end to create a Single-J stent (SJS). This stent will have only the top loop (in the kidney), and a straight end that sits in the bladder. The goal is to reduce discomfort while maintaining safety and effectiveness.

Participants in this study will already have a DJS in place from a prior procedure and will be undergoing planned ureteroscopy (URS) to remove their ureteric stone. At the end of that procedure, the modified SJS will be inserted. Participants will complete a short symptom questionnaire (USDT) both while the DJS is in and again after having the SJS, allowing a direct comparison. A flexible cystoscopy will be performed at stent removal to check for movement of the stent.

Participation involves minimal extra time, as all procedures would be happening as part of routine care. The only added steps are completing the symptom questionnaire and reviewing stent position at removal. Safety will be monitored closely throughout the study. Participation is entirely voluntary.

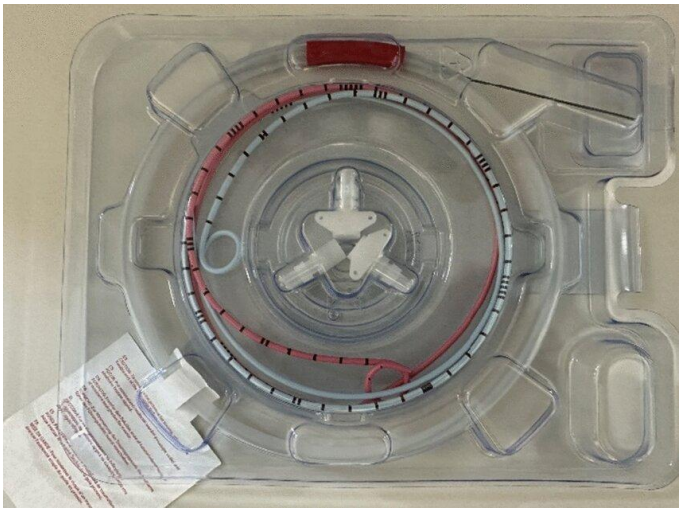

Figure. Cook Medical Bander Ureteral Diversion Stent Set. Standard of care in Cystectomy Ileal Conduit Surgery. https://www.cookmedical.com/products/uro_diversion_webds/

b. INTRODUCTION

Ureteric stenting is a cornerstone of postoperative management following ureteroscopy (URS) for ureteric stones. Although the Double-J (DJS) stent is the most commonly used device due to its anti-migration design, it is associated with significant stent-related discomfort and lower urinary tract symptoms (LUTS). A novel approach that modifies the DJS to create a Single-J stent (SJS) by removing its distal loop may offer symptom relief while maintaining clinical safety and efficacy.

This study is designed to investigate whether a modified SJS—created from an existing commercial DJS—offers a viable alternative in patients undergoing URS with pre-stenting. We hypothesize that the SJS will reduce urinary symptoms and discomfort while retaining sufficient positional stability.

This prospective interventional cohort study is, to our knowledge, the first Australian feasibility study evaluating post-URS outcomes with a modified SJS in a controlled, head-to-head comparison with prior DJS use in the same patients.

c. BACKGROUND INFORMATION

Stent-related symptoms are a common issue in endourology, often contributing to decreased patient satisfaction, increased healthcare use, and poorer quality of life. In recent years, interest has grown in reducing these adverse outcomes by innovating stent design. The majority of current studies on SJS devices are limited to case series, technical reports, or comparisons with DJS in non-post-URS contexts.

Literature from 10 key journal articles reveals the following:

- Migration is a major concern with SJS, but proper positioning and technique can mitigate this risk (Yang et al., Lai et al.).
- Several case series demonstrate successful SJS use without flexible cystoscopy or nephrostomy intervention (Yang et al., Koike et al.).
- The FaST trial (Bach et al.) and Ooms et al. study highlight patient-reported benefits with shorter stents or external catheters.
- Quality of life is significantly impacted by stent design; symptom questionnaires like USSQ and USDT are commonly used for assessment.
- Data on SJS migration show low rates of dislodgement in controlled settings with regular follow-up.

Despite some promising evidence, the literature lacks a structured, prospective head-to-head evaluation of modified SJS compared to DJS in the same patients—especially using validated symptom scores.

This study aims to address that gap by:

- Standardizing the SJS modification from a known commercial stent
- Including only patients who previously had a DJS to allow for intra-patient comparison

- Using USDT, a validated patient symptom questionnaire, to assess subjective outcomes
- Confirming migration rates by cystoscopic evaluation

The study aligns with clinical interest in improving patient experience post-URS while ensuring that no compromise occurs in clinical outcomes such as migration or infection rates.

4. STUDY OBJECTIVES

a. HYPOTHESIS

We hypothesise that:

- A modified Single-J stent (SJS), created by removing the distal loop off a standard fixed or multi-length Double-J stent, is feasible and safe for use following ureteroscopy (URS) in pre-stented patients.
- The SJS will result in significantly reduced stent-related symptoms compared to the standard DJS, as measured by the Ureteral Stent Discomfort Test (USDT).
- The SJS will demonstrate minimal risk of migration, with a clinically acceptable migration rate (defined as ≤5%).
- The SJS will be associated with no increase in adverse events relative to DJS, based on clinical review and literature precedent.

b. STUDY AIMS

Primary Aim:

- To evaluate the feasibility, safety, and symptom burden of a modified Single-J stent in patients undergoing URS for ureteric stones.

Secondary Aims:

- To assess and compare stent-related discomfort using USDT before and after SJS insertion (compared within the same patients who had prior DJS).
- To determine the migration rate of the SJS based on cystoscopic evaluation at time of stent removal.
- To document any procedure-related or stent-related complications (e.g., infection, haematuria, emergency re-intervention).
- To evaluate patient satisfaction with the SJS and willingness to undergo similar management in the future.
- To collect data on operative metrics, including time to insert the SJS and any intraoperative handling issues.

c. Outcome Measures

Primary Outcome Measure:

- SJS migration, assessed by flexible cystoscopy at removal and categorised by:
  - Tip within bladder
  - At ureteric orifice (UO)
  - In urethra
  - Not visualised

Secondary Outcome Measures:

- Change in USDT score before (with DJS in situ) and after (with SJS in situ) URS, assessed within-subject using a validated tool.
- Incidence of adverse events, including:
  - Symptomatic urinary tract infections (UTIs)
  - Haematuria requiring medical attention
  - Emergency department presentation or hospital readmission
  - Need for early SJS removal or re-intervention
- Ease of stent insertion and time taken, documented by operating surgeon.

5. Study Design

a. Study Type & Design & Schedule

This is a **prospective, single-arm, interventional feasibility study** conducted at a single tertiary care urology centre.

- **Study Type:** Interventional, non-randomised
- **Design:** Prospective cohort with intra-patient comparison (before-and-after)
- **Control Mechanism:** Within-subject comparison of symptoms (DJS vs SJS)
- **Sample Size:** Target recruitment of **40 participants maximum**
- **Study Duration per Participant:** Approximately 3–4 weeks, depending on timing of URS and stent removal
- **Total Study Duration:** Estimated 6 months including enrolment and follow-up

Assessment / Procedure	Screening Visit (Before or at enrolment)	URS Visit (Day 0)	Stent Removal Visit (Day 14 ± 2)
Eligibility assessment	✔		
Informed consent	✔	✔ (if not done earlier)	

Demographic and medical history collection	✔		
Baseline DJS symptom assessment (USDT)	✔	✔ (if not done earlier)	
URS procedure and stone treatment		✔	
Removal of pre-existing DJS		✔	
Insertion of modified Single-J stent		✔	
SJS symptom assessment (USDT)			✔
Stent migration assessment (cystoscopic exam)			✔
Adverse event monitoring		✔	✔
Final clinical review			✔

b. Standard Care and Additional to Standard Care Procedures

Participants will receive all aspects of routine care for ureteric stone management, including URS and post-operative stenting. The only investigational component is the use of a **modified SJS**, and the repeat use of the **USDT** symptom questionnaire.

Table 1: Standard Care Procedures

Visit/Timepoint	Standard Care Procedures
At emergency/ elective stent placement	Insertion of standard DJS
Pre-operative assessment	Routine pre-URS evaluation, bloods, imaging, consent
URS and laser lithotripsy	Standard endoscopic treatment with stone fragmentation and removal
Post-operative care	Monitoring, analgesia, discharge planning
Stent removal (2 weeks post-op)	Cystoscopic removal of stent under local anaesthesia or

sedation

Table 2: Additional to Standard Care (Study-Specific) Procedures

Visit/Timepoint	Additional/Research Procedures
Pre-URS (with DJS in situ)	Administer **USDT questionnaire.** Patient's pre-op CT scan will be reviewed to measure ureteral length
At URS (intra-op)	Replace DJS with **modified SJS** (distal loop of DJS trimmed)
Post-URS (day of discharge or review)	Record intra-op findings and SJS placement data
Stent removal (at 2-week cystoscopy)	Administer **USDT questionnaire**, assess **stent migration location**, collect feedback

c. RANDOMISATION

As this is a **non-randomised, single-arm feasibility study**, no randomisation procedures will be used. All enrolled participants will receive the same intervention. The study design allows for each participant to serve as their own control by comparing their symptoms between two different time points (with DJS vs with SJS).

d. STUDY METHODOLOGY

Recruitment:

- Patients presenting to urology outpatient clinics or emergency departments who are already pre-stented with a DJS for a unilateral ureteric stone will be screened.
- Suitable candidates will be provided with verbal and written study information, and informed consent will be obtained.

Intervention:

- At the time of their scheduled URS and laser lithotripsy, the standard DJS will be removed.
- A modified SJS will be fashioned from a Bander ureteral stent by shortening it to 28 cm from the end of the proximal curve.
- A 2-0 monofilament non-absorbable prolene suture will be anchored to the distal end of the SJS. Measured to 7cm
- The modified SJS will be placed in standard fashion under fluoroscopic guidance.

Symptom Assessment:

- All participants will complete the USDT while the DJS is in situ (prior to URS).
- The same questionnaire will be completed again while the SJS is in place (2 weeks post-URS at time of stent removal).

Migration Assessment:

- At time of SJS removal via flexible cystoscopy, migration status will be categorised as follows:
    - SJS tip **freely floating in bladder**
    - SJS tip **at ureteric orifice**
    - SJS tip **in urethra**
    - SJS tip **not visualised**

Adverse Events Monitoring:

- Participants will be asked about emergency presentations, symptoms of infection, haematuria, or intolerable discomfort during the stent period.
- All adverse events (AEs) related to the modified SJS will be recorded and monitored. Any serious adverse events (SAEs) will be reported to the Human Research Ethics Committee (HREC) in accordance with local governance procedures.
- An Adverse Event (AE) is any untoward medical occurrence in a participant. A Serious Adverse Event (SAE) is any event that results in death, is life-threatening, requires hospitalisation, or results in significant disability.
- All SAEs will be reported to the Principal Investigator within 24 hours of site awareness.
- The PI will report SAEs to the Austin Health HREC and Research Governance Office within required timelines (usually within 72 hours) as per institutional and NHMRC policy.
- AEs will be recorded in the participant's medical record and the study CRF/REDCap database.
- Participants experiencing harm will receive appropriate medical care, and any study-related events will be documented and reviewed in safety monitoring.
-

Data Collection:

- Data on demographics, stone characteristics, intraoperative findings, and stent-related complications will be collected and stored securely in a REDCap database.
- All clinical data, USDT scores, and cystoscopic assessments will be recorded in secure electronic case report forms (eCRFs). Study data will be stored in accordance with Good Clinical Practice (GCP) and institutional data governance policies. All identifying patient information will be de-identified in analysis datasets.

Ureteral Stent Discomfort Test							
Name:							
Date:			Age:		Sex:		
Date of stent insertion:							
Time with indwelling ureteral stent:							
Do you currently have an indwelling ureteral stent?			Yes		No		
	Ureteral Stent Discomfort Test	**Never**	**Very seldom**	**Seldom**	**Sometimes**	**More than half the time**	**Almost always**
		0	1	2	3	4	5
1	How often have you had to urinate less frequently than every two hours?						
2	How often have you had the sensation of not emptying your bladder?						
3	How often have you found it difficult to postpone urination?						
4	How often have you presented with urine leakage?						
5	How often have you had a burning sensation during urination?						
6	How often have you observed blood in your urine?						
		Absent	**Mild**	**Moderate**	**Severe**		
		0	1	2	3		
7	If you have had lower back pain (lumbalgia), how would you describe it?						
8	If you have had lower abdominal pain (suprapubic region), how would you describe it?						
		Never	**Seldom**	**Very seldom**	**Sometimes**	**More than half the time**	**Almost always**
		0	1	2	3	4	5
9	In general, has the ureteral stent made you unable to walk, do exercise, or perform daily activities?						
10	Since ureteral stent placement, how often have you experienced pain or discomfort during sexual intercourse?						
11	Since ureteral stent placement, how often have you had to take an analgesic or pain medication to lessen the discomfort from the ureteral stent?						
12	Since ureteral stent placement, how often have you had to see a physician or go to the emergency room due to the discomfort from the ureteral stent?						
13	Since ureteral stent placement, how often has the ureteral stent negatively affected your daily life?						

Urinary symptoms	/30
Pain	/6
Daily life	/5
Sexual life	/5
Medical care/analgesics	/10
QoL	/5
TOTAL SCORE	/61

6. Study Population

a. Recruitment Procedure

Pre-Screening Identification of Eligible Participants

- **Source**: Patients will be identified from the elective surgical booking list for ureteroscopy (URS), laser lithotripsy, and ureteric stent exchange procedures.
- **Referrals** are received through standard hospital pathways, including outpatient urology clinics, emergency department follow-up, and internal referrals by urology registrars/consultants.
- **Clinical screening** for eligibility will be performed by the principal investigator or a designated urology registrar by reviewing medical records and operation bookings.

Recruitment Approach

- Once a patient is confirmed to be undergoing elective URS with pre-existing Double-J stent in place:
    - Initial contact will be made via telephone or in-person in clinic at least several days prior to the scheduled URS.
    - Patients will be informed that they are eligible for a research study evaluating a modified ureteric stent (Single-J stent or SJS).
    - A **Participant Information Sheet and Consent Form (PICF)** will be emailed or posted, or provided in person, depending on timing and logistics.
- On the day of surgery (prior to anaesthesia):
    - The research team will be available to answer any additional questions.
    - Informed consent will be formally obtained before any study-related procedures.

Eligibility Confirmation

- Final confirmation of eligibility will occur on the day of surgery following:
    - Verification of pre-stented status
    - Absence of active infection or anatomical contraindications to SJS
    - Reaffirmation of voluntary participation and comprehension of the study

Recruitment Duration

- Recruitment is expected to occur over a **6-month period**, aiming to enrol **40 patients** total.

Equity and Accessibility

- All eligible patients will be approached regardless of gender, race, or socioeconomic background.
- Consideration will be given to:

- Providing interpreters for patients with limited English (if feasible)
- Ensuring all patients are given equal opportunity to participate and adequate time to consider involvement

Reimbursement

- No financial incentives will be offered. Participation is voluntary and all stent procedures are part of standard care, aside from the investigational stent modification.

Target Population:

- Adults aged ≥18 years undergoing elective ureteroscopy (URS) and stent exchange for ureteric stone management.
- All participants will have a pre-existing Double-J stent (DJS) in situ prior to URS.

Rationale:

- Pre-stented patients can provide direct symptom comparison between DJS and the investigational Single-J stent (SJS).
- This cohort closely reflects standard clinical practice, enhancing real-world relevance.

b. Inclusion Criteria

Inclusion Criteria:

- Age ≥18 years.
- Undergoing elective URS and stent exchange for ureteric stone disease.
- Already pre-stented with a Double-J ureteric stent prior to URS.
- Able and willing to provide informed consent.
- Sufficient English proficiency to complete symptom questionnaires (USDT).

c. Exclusion Criteria

Exclusion Criteria:

- Single kidney or bilateral ureteric disease.
- History of ureteric strictures or prior ureteric reconstruction.
- Pregnancy or breastfeeding.

- Active urinary tract infection at time of URS.
- Immunocompromised state (e.g., ongoing chemotherapy, high-dose steroids).
- Any contraindication to ureteric stenting or flexible cystoscopy.
- Patients unwilling or unable to comply with follow-up procedures.
- Complex cases identified intra-op
    - Very large ureteric stone (>10mm), impacted stone, stone in intramural ureter, difficult stent, significant bleeding after stenting

d. CONSENT

Consent Process:

- Initial contact will occur via phone or in person once a patient is identified on the elective surgical booking list for URS and stent exchange.
- Consent obtained during preoperative consultation or on day of URS, prior to any study-specific procedures.
- Informed consent will be obtained by the **Principal Investigator** or **delegated urology registrar or resident medical officer** who is listed on the Site Delegation Log.
- The **Participant Information Sheet and Consent Form (PICF)** will be provided (via email, post, or hard copy) and explained to the patient during this contact.
- On the day of surgery, prior to any study-related procedures and before anaesthesia, the participant will have the opportunity to ask questions.
- Written informed consent will be obtained **before** proceeding with stent modification and data collection.

Consent Documentation:

- Signed original consent form retained in participant file.
- Copy provided to participant.
- Consent status recorded in secure database

What will participants be told about the study?

Participants will be informed of the following key elements:

- **Study Background**:
    - Ureteric stents are routinely used after URS for stone treatment.
    - Standard stents (Double-J) are associated with common symptoms like pain, urinary urgency, frequency, and discomfort.
    - This study is trialling a modified Single-J stent, created from an existing Bander Ureteral Stent, which may reduce these symptoms.
- **Study Purpose**:
    - To evaluate if the modified SJS is safe, feasible, reduces stent symptoms, and does not migrate.
- **What Participation Involves**:
    - Completing a USDT questionnaire before URS (while the standard DJS is in situ) and again before stent removal (with SJS in situ).
    - Undergoing the usual URS and stent insertion procedure, except the stent used will be modified.
    - Attending follow-up for flexible cystoscopy and stent removal (~7–10 days later), where migration will be assessed.
    - Participation lasts for approximately 2–3 weeks.
- **Risks**:
    - **Standard risks** related to URS and stent use:
        - Haematuria
        - Dysuria
        - Urinary tract infection
        - Pain or discomfort
        - Stent migration (rare)
    - **Specific risks of modified SJS**:
        - Unknown risk of stent migration due to loss of distal loop
        - Limited existing data on patient outcomes using SJS
        - Possibility of needing an earlier intervention if complications arise (e.g. migration, pain)
- **Benefits**:
    - Direct benefits to participants are not guaranteed.

- Potential for reduced stent symptoms and discomfort.
- Contribution to research aimed at improving stent tolerability and quality of life for future patients.

- **Confidentiality**:
  - Data will be securely stored and de-identified.
  - Results may be published, but participants will not be identifiable.
- **Right to Withdraw**:
  - Participation is voluntary.
  - Participants may withdraw at any time without impact on their medical treatment or relationship with treating clinicians.

7. PARTICIPANT SAFETY AND WITHDRAWAL

a. RISK MANAGEMENT AND SAFETY

- **Known Risks**:
  - Risks inherent to ureteroscopy (URS) and ureteral stenting include:
    - Haematuria (blood in urine)
    - Dysuria (painful urination)
    - Urinary tract infection (UTI)
    - Stent-related discomfort and pain
    - Potential stent migration or obstruction
  - Risks specifically related to the **modified Single-J stent (SJS)**:
    - Possible increased risk of stent migration due to absence of distal loop
    - Unknown impact on urinary symptoms compared to standard Double-J stent (DJS)
    - Need for additional intervention if migration or obstruction occurs
  - Allergic or adverse reactions to materials are expected to be similar to those for standard stents.
- **Safety Monitoring**:
  - Participants will be monitored closely post-URS and during stent removal cystoscopy.

- Any adverse events (AEs), serious adverse events (SAEs), or device-related complications will be documented and reported per institutional policy.
- The clinical care team will manage all complications promptly, including the possibility of stent replacement or early removal.
- An Adverse Event (AE) is any untoward medical occurrence in a participant. A Serious Adverse Event (SAE) is any event that results in death, is life-threatening, requires hospitalisation, or results in significant disability.
- All SAEs will be reported to the Principal Investigator within 24 hours of site awareness.
- The PI will report SAEs to the Austin Health HREC and Research Governance Office within required timelines (usually within 72 hours) as per institutional and NHMRC policy.
- AEs will be recorded in the participant's medical record and the study CRF/REDCap database.
- Participants experiencing harm will receive appropriate medical care, and any study-related events will be documented and reviewed in safety monitoring.

- **Mitigation Strategies**:
  - Only patients who have been pre-stented with standard DJS are included, providing baseline symptom comparison.
  - Migration will be directly visualized during cystoscopic stent removal, allowing timely intervention.
  - Participants will have clear instructions to report symptoms such as severe pain, fever, or signs of infection immediately.
- **Ethical and Regulatory Compliance**:
  - The study follows Good Clinical Practice guidelines.
  - Safety data will be reviewed regularly by the Principal Investigator.
  - The study will be halted or modified if unacceptable safety concerns arise.

b. HANDLING OF WITHDRAWALS

- **Participant Rights**:
  - Participation is entirely voluntary.
  - Participants may withdraw from the study at any time and for any reason without penalty or loss of medical care.
- **Withdrawal Process**:

- If a participant decides to withdraw, they will be asked (but not required) to provide a reason to improve study processes.
- Participants withdrawing prior to stent removal will receive appropriate clinical follow-up and standard care.

- **Data Handling Upon Withdrawal**:
  - Data collected up to the point of withdrawal will be retained and included in analyses unless the participant requests otherwise.
  - Withdrawal will be documented clearly in study records.
- **Early Study Withdrawal Criteria**:
  - Participants may be withdrawn early for safety reasons, including but not limited to:
    - Severe adverse events related to the stent
    - Significant protocol violations
    - Investigator decision based on clinical judgment

c. REPLACEMENTS

- **Replacement of Withdrawn Participants**:
  - Participants who withdraw before completion of the study will **not** be replaced.
  - The study sample size calculation accounts for potential withdrawals and loss to follow-up to maintain statistical power.
- **Rationale**:
  - Due to the nature of the intervention and follow-up timeline (~2–3 weeks), replacement recruitment may delay study completion and is not planned.

8. STATISTICAL METHODS

a. SAMPLE SIZE ESTIMATION & JUSTIFICATION

- The study aims to detect a clinically meaningful difference in ureteral stent symptoms as measured by the USDT score between Double-J stent (DJS) and Single-J stent (SJS) within the same patients.
- Based on prior similar studies using ureteral stent symptom questionnaires (e.g., Bostanci et al., Betschart et al.), a minimum detectable difference of approximately 15% in symptom scores is considered clinically relevant.

- To account for within-subject paired comparisons and variability observed in previous trials, a sample size of **40 participants** has been chosen.
- This number provides sufficient precision for feasibility and exploratory objectives and allows for attrition or loss to follow-up.

b. Power Calculations

- Assuming a two-sided significance level (alpha) of 0.05 and a power of 80%, the sample size of 45 achieves adequate power to detect a 15% difference in USDT scores between the two stent types.
- This calculation assumes a moderate effect size (Cohen's d approximately 0.5) based on variability reported in published ureteral stent symptom studies.
- The paired design enhances statistical power by reducing inter-subject variability.

c. Statistical Methods To Be Undertaken

- **Primary Analysis**:
    - Comparison of USDT scores with DJS and SJS within participants using the paired t-test for normally distributed data.
    - If normality assumptions are violated, the **Wilcoxon signed-rank test** will be applied.
- **Secondary Analysis**:
    - Migration rates (categorical) will be summarized using frequencies and percentages.
    - Associations between migration and baseline characteristics will be examined using **Chi-square** or **Fisher's exact tests**.
- **Descriptive Statistics**:
    - Demographics and baseline characteristics will be summarized with means ± SD, medians and IQR, or counts and percentages as appropriate.
- **Missing Data**:
    - Complete-case analysis will be primary.
    - Sensitivity analyses with multiple imputation will be performed if missingness exceeds 5%.
    - **Statistical significance**: Set at $p < 0.05$.
    - **Software**: Analyses performed using SPSS, Stata, or R.

9. Storage of Blood and Tissue Samples

a. Details of where samples will be stored, and the type of consent for future use of samples

Not applicable

10. Data Security & Handling

a. Details of where records will be kept & How long will they be stored

- All study-related records, including electronic case report forms (eCRFs), will be securely stored in a **REDCap (Research Electronic Data Capture)** database hosted on a secure institutional server.
- Physical documents such as signed consent forms will be stored in locked filing cabinets within restricted-access areas of the study site.
- Data will be retained for a minimum of **15 years** following study completion, in accordance with institutional policies and relevant regulations.
- After the retention period, data will be securely destroyed or anonymized to protect participant confidentiality.

b. Confidentiality and Security

- Participant data entered into REDCap will be identified only by a unique study ID number; no personally identifiable information will be included in the database.
- Access to the REDCap system is restricted to authorized study personnel via secure login credentials.
- All data transfers will use encrypted connections (HTTPS/SSL) to maintain confidentiality.
- Data handling will comply with institutional data protection policies and applicable privacy legislation (e.g., GDPR or local equivalents).
- Any paper-based records will be handled in accordance with confidentiality protocols and kept in locked cabinets within secure facilities.

c. Ancillary data

- Additional data collected for ancillary analyses (e.g., demographic, clinical baseline data, procedure details, ureter length measured from Computed Tomography) will be stored alongside primary outcome data within the REDCap database.
- Ancillary data will be governed by the same confidentiality and retention policies as the main study data

11. References

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