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Two single-arm, multicentre unblinded first-in-human trials, including two phases and a qualitative substudy investigating a novel ureteric stent in kidney stone patients and oncology patients to determine the reduction of encrustation, biofilm deposition and complications compared to a conventional JJ stent (CASSETTE)

Submission date
08/01/2025

Recruitment status
Recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
04/11/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A key problem with ureteric stents is that they can become narrowed or blocked by a build-up of calcium (like scaling in your kettle) or by bacteria (like the gunge in the plughole of your sink or bath). When this happens, patients may develop a urine infection, which needs to be treated with antibiotics. If a patient has many infections, the bacteria can become resistant to antibiotics, so that it becomes more difficult to treat the infections. If the stent is completely blocked, patients need to return to hospital for another operation to replace the stent.
Researchers in the Department of Mechanical Engineering at the University of Southampton have designed a new stent, which may be less prone to blockages. It has holes in the side with unique designs to improve the flow of urine and to prevent the build-up of calcium and bacteria. Therefore these stents may last longer before they need to be replaced, and patients may need to come to hospital less often to have the stent changed, which could improve their quality of life.
In this trial, we want to test these stents in humans for the first time. We need to prove whether they are safe and acceptable to patients, and whether they work as well as we predict.

Who can participate?
Patients aged 18 years or older with kidney stones or abdominal cancers, with previous experience of ureteric stents and clinical indication for ureteric stents.

What does the study involve?
Insertion and removal of the novel stent, a number of follow up questionnaires for patients to answer, and an optional qualitative interview asking about patients and clinicians experience with a stent

What are the possible benefits and risks of participating?
This trial provides patients an opportunity to benefit from the novel ureteric stent which might be less prone to blockages. We do not anticipate any difference in risk between the novel stent to any standard stents however, there are potential risks with standard stents that may also occur with the novel stent. The risks and their associated treatments are expected to be exactly the same as if patients received a standard stent and were not part of this clinical trial. For example, stent fracture is a potential risk, which occurs in less than 1 in 100 procedures. If the stent fractures during insertion, the surgeon may replace the fractured stent with a new novel stent or proceed with a standard stent depending on which they feel is best for the patient.

Where is the study run from?
Southampton Clinical Trials Unit, University of Southampton (UK)

When is the study starting and how long is it expected to run for?
August 2024 to December 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Invention for Innovation (I4I) Product Development Award (PDA) programme (UK)

Who is the main contact?
Sinead Helyar, cassette@soton.ac.uk

Contact information

Type(s)

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Additional identifiers

Integrated Research Application System (IRAS)
323840

Central Portfolio Management System (CPMS)
63424

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202935

Protocol serial number
Grant Code:

Study information

Scientific Title
Two single-arm, multicentre unblinded first-in-human trials, including two phases and a qualitative substudy investigating a novel ureteric stent in kidney stone patients and oncology patients to determine the reduction of encrustation, biofilm deposition and complications compared to a conventional JJ stent (CASSETTE)

Study objectives
The novel ureteric stent is safe for use in patients and is not inferior to currently available standard stents in terms of safety and clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/08/2024, North East - York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 24/NE/0121

Primary study design
Interventional

Study design
Non-randomized; Both; Design type: Treatment, Process of Care, Physical, Management of Care, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ureteric stent in kidney stone patients and oncology patients

Interventions
To test these new stents, we will run 'First-in-Human' trials to assess safety, performance, and patient acceptability, providing data for analysis and development of wider clinical trials. We have identified two clinical subgroups where this device may offer advantages against E&B:
Short-term: Patients with kidney/renal stones who require stent insertion (<4 weeks indwelling time).
Long-term: Patients with abdominal/pelvic cancers compressing the ureters (25 weeks indwelling time).

We expect the device to have similar performance and safety in both groups. If it underperforms in either group, it is likely to be the cancer group, due to disease characteristics. We therefore plan to assess the use of the device in both groups separately and will only proceed to assess in the cancer group if there are no safety concerns identified in the stone group.

(Up to 8 weeks prior to the day of surgery)
The clinical team at site will discuss the upcoming surgery with the patient as well as their potential participation in the study. This consultation can take place face-to-face or remotely (video or telephone call). Patients will have the opportunity to discuss their potential participation in the study and any questions with the clinical team.
If the patient is willing to consent to take part in the study, informed consent for participation in the study will be taken on the day of surgery at their pre-surgery assessment. This includes consenting to the completion of questionnaires, provide information about some information relating to any stents they may have had in the past, removal of the novel ureteric stent and a collection of a urine sample. Once the patient has provided informed consent, the clinical team will then register the patient on the trial database. This will then generate a trial ID number for the patient. The patient has the option to consent to their contact details (telephone, email address, postal address) being shared with the qualitative researcher if the patient is interested in taking part in a telephone/video call interview about their
experiences with ureteric stents.
If a patient does not wish to take part in the trial but is interested in sharing their experiences of ureteric stents, the clinical team can take consent for sharing the patient's contact details (telephone, email address, postal address) with the qualitative interviewer at the University of Southampton.
The clinical team will share contact details of patients who agreed to be contacted regarding the qualitative interview with the qualitative researcher, see protocol section 6.7.3
The clinical team will complete a registration form with the trial ID number for the patient and send a copy to cassette@soton.ac.uk.

On the day of surgery (Kidney stone patients)
• The clinical team will take informed consent
• Re-confirm patient eligibility (including standard of care pregnancy test – required to confirm eligibility)
• Patient history form completed
• Physical Exam
• Check for Adverse Events/Device Events
• Register patient onto the database
• Prior to stent insertion, patients will be asked to complete CASSETTE (Kidney Stone) Patient Questionnaire –BASELINE questionnaire online (or paper copy)
Patient Questionnaire – BASELINE* questionnaire on paper
*Kidney stone baseline (no current stent in place) questionnaires include:
- Subject demographics
- Short Version Stent Quality of Life (no current stent in place)
- USI-QoL – Stone disease
*Kidney stone baseline (current stent in place) questionnaire includes:
- Subject demographics
- Short Version Stent Quality of Life (stent in place)
- USI-QoL – Stone disease
- Ureteric Stent Symptoms Questionnaire (with a stent in place) [USSQ]
The clinician will then perform surgery (for the purpose of this study this is called surgery 1) and

inserts the novel ureteric stent (this may be a replacement of pre-existing stent). Any adverse events or device deficiencies occurring during the surgery as a result of the removal of the old stent, as well as the insertion of the novel stent must be recorded on the database.

Twenty-four hours (24h) post Surgery 1
Patients will be asked to complete CASSETTE (Kidney Stone) Patient In Situ Questionnaire - 24hr after Surgery 1* questionnaire online, or if completed on paper, the questionnaires will be returned to the site team using a freepost envelope.
*Kidney stone in situ (24 h after surgery 1) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- USI-QoL – Stone disease
- Ureteric Stent Symptoms Questionnaire (with a stent in place) [USSQ]
Within 24 h prior to Surgery 2 (Removal of stent) - <4 weeks indwelling time
Long-term: Patients with abdominal/pelvic cancers compressing the ureters (25 weeks indwelling time).
Patients will be asked to complete CASSETTE (Kidney Stone) Patient In Situ Questionnaire - Surgery 2* questionnaire online, or if completed on paper, the participants should bring the questionnaires with them to the day of removal surgery)
*Kidney stone in situ (Surgery 2) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- USI-QoL – Stone disease
- Ureteric Stent Symptoms Questionnaire (with a stent in place) [USSQ]

Day of Surgery 2
The clinical team performs surgery 2 and removes the experimental (novel) ureteric stent (and replaces with standard of care ureteric stent as applicable). For kidney stone patients, this will take place approximately 4 weeks after insertion. The novel ureteric stents can be removed earlier if deemed necessary by the treating clinician. At this stage, the clinical team will collect information relating to any adverse events and device deficiencies and record these on the database.
The clinical team will collect a urine sample and the experimental (novel) ureteric stent following the procedures detailed in the laboratory manual. The clinical team will perform any standard of care procedures as required, including performing safety blood tests. These will be detailed in the patients' medical notes and will only be collected as part of the trial data if clinically relevant.

Two to three (2-3) weeks post-Surgery 2
Patients will be asked to complete CASSETTE (Kidney Stone) Patient Questionnaire – Post Removal surgery* questionnaire online or if completed on paper, the questionnaires will be returned to the site team using a freepost envelope.
*Kidney stone (post-removal surgery) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- USI-QoL – Stone disease
- Ureteric Stent Symptoms Questionnaire (after stent removed) [USSQ]

TRIAL PROCEDURES – ONCOLOGY PATIENTS
Day of Surgery 1
• The clinical team will take informed consent
• Assessment of patient eligibility (including standard of care pregnancy test – required to confirm eligibility)

• Patient history form completed
• Physical Exam
• Check for Adverse Events/Device Events
• Register patient onto the database
• Prior to novel ureteric stent insertion, patients will be asked to complete CASSETTE (Oncology) Patient Questionnaire – BASELINE* questionnaire on paper
*Oncology baseline (no current stent in place) questionnaires include:
- Subject demographics
- Short Version Stent Quality of Life (no current stent in place)
- EQ-5D-5L
*Oncology baseline (current stent in place) questionnaire includes:
- Subject demographics
- Short Version Stent Quality of Life (stent in place)
- EQ-5D-5L
- Ureteric Stent Symptoms Questionnaire (in-situ) [USSQ]
The clinician will then perform surgery (for the purpose of this study this is called surgery 1) and inserts the novel ureteric stent (this may be a replacement of pre-existing stent). Any adverse events or device deficiencies occurring during the surgery as a result of the removal of the old stent, as well as the insertion of the novel stent must be recorded on the database.

Twenty-four hours (24 h) post-Surgery 1
Patients will be asked to complete CASSETTE (Oncology) Patient In Situ Questionnaire - 24hr after Surgery 1* questionnaire online, or if completed on paper, the questionnaires will be returned to the site team using a freepost envelope.
Oncology in situ (24 h after surgery 1) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- EQ-5D-5L
- Ureteric Stent Symptoms Questionnaire (with a stent in place) [USSQ]

Halfway between Surgery 1 and Surgery 2
Patients will be asked to complete CASSETTE (Oncology) Patient In-Situ Questionnaire - Halfway* questionnaire online, or if completed on paper, the questionnaires will be returned to the site team using a freepost envelope.
*Oncology in situ (Halfway) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- EQ-5D-5L
- Ureteric Stent Symptoms Questionnaire (with a stent in place) [USSQ]
Within 24hrs prior to Surgery 2 (Removal of stent) - 25 weeks indwelling time

Patients will be asked to complete CASSETTE (Oncology) Patient In-Situ Questionnaire - Surgery 2* questionnaire online, or if completed on paper, the participants should bring the questionnaires with them to the day of removal surgery)
*Oncology in situ (Surgery 2) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- EQ-5D-5L
- Ureteric Stent Symptoms Questionnaire (with a stent in place) [USSQ]

Day of Surgery 2
The clinical team performs surgery and removes the novel ureteric stent (a standard of care

ureteric stent may be replaced during this surgery as required). For oncology patients, this will take place approximately 25 weeks after insertion. The novel ureteric stents can be removed earlier if deemed necessary by the treating clinician. The clinical team will collect a urine sample and the experimental (novel) ureteric stent following the procedures detailed in the laboratory manual. These will be analysed. The clinical team will perform any standard of care procedures as required, including performing safety blood tests. These will be detailed in the patients' medical notes and will only be collected as part of the trial data if clinically relevant.

Two to three (2-3) weeks post-Surgery 2
Patients will be asked to complete CASSETTE (Oncology) Patient Questionnaire – Post Surgery 2* questionnaire online or if completed on paper, the questionnaires will be returned to the site team using a freepost envelope.
*Oncology (post-Surgery 2) questionnaire includes:
- Antibiotics/Hospitalisation
- Short Version Stent Quality of Life
- EQ-5D-5L
- Ureteric Stent Symptoms Questionnaire (after stent removal) [USSQ]

TRIAL PROCEDURES – QUALITATIVE INTERVIEWS
Qualitative interviews – Clinician cohort
At least ten clinicians (until sample saturation), who have been involved in managing patients in this trial with the novel ureteric stents, or those who may be interested in using the novel ureteric stent will initially be contacted by the CASSETTE Principal Investigators from each site to make them aware of the chance to participate in a qualitative interview and each clinician will be invited to email the CASSETTE study team to express their interest in participating. The CASSETTE study team will then share their details with the qualitative researcher at the University of Southampton. The qualitative researcher will invite clinicians to an interview (up to 45 minutes by telephone or video call). All clinicians will be given a copy of the clinician participant information sheet about these interviews. They will also be sent an email, a text or an invitation letter prior to their qualitative interview to remind them of their appointment if they wish to take part. The interviews with the clinicians will take place towards the last 3 months of the trial.

Qualitative interviews – Patient cohort
Patients will have the option to consent to take part in the qualitative interviews, at the same time as consenting to the main trial. If they do not wish to take part in the main trial, they will still have the option to provide consent for their details to be shared with the qualitative researcher. The qualitative researcher (at the University of Southampton) will contact the patients who consented to their contact details being shared and discuss any potential questions and to arrange a time to speak with them by telephone or video call. They will also be sent an email, a text, or an invitation letter prior to their qualitative interview to remind them of their appointment. The interviews with participants will take place after their stent has been removed and the completion of the follow-up questionnaire.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Stent failure, defined as any of:
1. A stent change earlier than planned (oncology only)
2. Need for additional surgical or radiological intervention
3. Kidney failure (evidenced by acute kidney injury (AKI) on blood tests (eGFR or creatinine kidney function tests) and/or worsening hydronephrosis on imaging Summary method: Frequency and percentage of people experiencing any stent failure
Time frame: from enrolment to stent removal (~4 weeks for kidney cohort), (~25 weeks for oncology cohort)

Key secondary outcome(s)
1. Extent of encrustation and biofilm (E&B) measured using:
1.1. Cell culturing (CFU counts per ml per bacterial microorganism)
1.2. Dwell time
1.3. Imaging (selected samples of stents will be examined using non-contact, non-destructive episcopic-differential-interference-contrast (EDIC) microscopy allowing imaging of the surface with the biofilm in-situ and colonisation by bacteria – when needed)
Time frame: from enrolment to stent removal (~4 weeks for the kidney cohort, ~25 weeks for the oncology cohort)
2. Clinical outcomes:
2.1. Individual components of the primary outcome
2.2. Urinary symptoms
2.3. Infections
Time frame: from enrolment to completion of patient questionnaires 2-3 weeks post-surgery 2 (~4 weeks for the kidney cohort), 2-3 weeks post-surgery 2 (~25 weeks for the oncology cohort)
3. Quality of life measured using study-specific baseline (pre-stent insertion/implantation), in situ (stent inserted/implanted) and post-surgery (post-stent removal) questionnaires. Time frame: within first month of stent removal for participants (~4 weeks for the kidney cohort, ~25 weeks for the oncology cohort)
4. Patient experience in having the novel ureteric stent inserted and reason for participation in the trial, assessed using 30–45-minute qualitative interviews with oncology and kidney stone cohorts and an inductive thematic analysis of interview transcripts. Time frame: from enrolment to stent removal (~4 weeks for the kidney cohort, ~25 weeks for the oncology cohort)

Other pre-specified outcomes:
1. Extent of encrustation and biofilm (E&B) measured using:
1.1. Weight: Stents will be weighed post-removal upon arrival at the microbiology lab
1.2. Flow study (pressure value): A section of the retrieved stent will be used for flow study. The part will be placed into a larger diameter tube. DI water/saline is injected using a pump into the inlet of the external tube and pressure sensor is connected to the inlet tube. Pressure readings will be captured per stent. Imaging (selected samples of stents will be examined using non-contact, non-destructive SEM (scanning electron- microscopy) allowing imaging of the surface with the biofilm in situ and colonisation by bacteria – when needed).
Time frame: after surgery 2 for the kidney stone cohort (~4 weeks) and surgery 2 for the oncology patients (~25 weeks)

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Ureteric stents clinically indicated either due to kidney stones or abdominal/pelvic cancers compressing ureters
3. Previous experience with ureteric stents
4. Awaiting insertion/replacement of stents
5. Ability to give consent
6. Ability to interact with the study documentation
7. Sufficient English to complete study documentation and questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Expected survival <4 months
2. Unfit for stent insertion
3. Unable to comply with study processes
4. Pregnancy occurring prior to stent insertion
5. Planned stent removal is not at the same hospital as the stent insertion

Date of first enrolment
15/08/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton

United Kingdom
SO16 6YD

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

In order to meet our ethical obligation to responsibly share data generated by interventional clinical trials, SCTU operate a transparent data sharing request process. As a minimum, anonymous data will be available for request from three months after publication of an article, to researchers who provide a completed Data Sharing request form that describes a methodologically sound proposal, for the purpose of the approved proposal and if appropriate a signed Data Sharing Agreement. Data will be shared once all parties have signed relevant data sharing documentation. Researchers interested in our data are asked to complete the Request for Data Sharing form (CTU/FORM/5219) [template located on the SCTU website, https://www.southampton.ac.uk/ctu] to provide a brief research proposal on how they wish to use the data. It will include the objectives, what data are requested, timelines for use, intellectual property and publication rights, data release definition in the contract and participant informed consent etc. If considered necessary, a Data Sharing Agreement from Sponsor may be required.

IPD sharing plan summary

Available on request