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Memokath in ureteric stricture study

Submission date	Recruitment status	[X] Prospectively registered
26/01/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2023	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Urine from the kidney drains via the ureter into the bladder. The ureter can be blocked by benign and malignant conditions. Patients who are not suitable for reconstructive surgery are offered the insertion of a JJ stent (JJ) under anaesthesia (standard care). JJ is a tube made of plastic material that bypasses the obstruction. It has ends in the kidney and bladder, which is the cause of stent symptoms (urinary frequency, urgency, dysuria [painful urination], incomplete emptying; flank and suprapubic pain; incontinence, and haematuria [blood in the urine]). It reduces quality of life (QOL) in 80% of patients and requires 3 to 6 monthly changes. Memokath-051 Double-cone (MK-051) is a nickel-titanium alloy stent. This stent resides within the ureter, so there is no irritation of the bladder or kidney. According to the National Institute for Health and Care Excellence (NICE) and the manufacturer, there is no planned stent change. MK-051 does not cause stent symptoms. This potentially improves QOL and reduces hospital visit treatment costs. NICE reviewed the published literature and suggested that the evidence for MK-051 over JJ is from small, poorly reported, retrospective studies. This study aims to observe the quality of life improvement with MK-051 urinary stent over the JJ stent and the longevity of the MK-051 for over 2 years.

Who can participate?
Patients aged over 18 years who are on a JJ stent that is being changed periodically to maintain kidney function

What does the study involve?
The researchers will record all the participants' medical history and details of their medications and other treatments. Participants fill in questionnaires, give blood and urine samples to check for infection and kidney function, and undergo x-rays and nuclear medicine scans to monitor their condition. As with all x-rays there are health and safety issues to consider. Samples are refrigerated and stored after testing and then destroyed as per NHS laboratory policy. Once this is done participants will enter the first stage of the study and a date will be arranged for the insertion of MK-051. After the successful insertion of MK-051 participants will enter the final stage of the study and will have follow-up for up to 2 years

What are the possible benefits and risks of participating?
The benefit of taking part in this research is that the research and medical team will monitor participants more closely, so any side effects or issues that arise can be treated quickly. The

results of the study will provide reliable information on quality-of-life improvement for patients on MK-051, and will help doctors when they are advising other patients who need this stent in the future. Due to the change of the stents occurring less often, there will hopefully be lower costs involved fewer operations and visits.
There is a risk of stent migration or stone formation (encrustation). In such events the MK-051 stent can be removed under anesthesia if necessary. There is a possibility for reinsertion of the MK-051 or a double JJ Stent. Sometimes the doctor may choose to insert a nephrostomy under local anaesthesia if participants are not fit to undergo a general anaesthetic procedure. A nephrostomy is a small tube inserted through the skin into the kidney to allow urine to drain from the kidney into a collecting bag outside the body.
Participants will receive renal imaging with nuclear medicine scans in addition to a regular x-ray of their kidneys and x-ray fluoroscopy during the insertion of the stent. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will increase the chance of this happening to you by about 0.03% (https://www.cancerresearchuk.org/health-professional/cancer-statistics/risk/lifetime-risk). Similar radiation exposure happens with standard care (JJ stent) when undergoing periodic stent changes.

Where is the study run from?
James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2021 to September 2026

Who is funding the study?
1. PNN Medical A/S (Denmark)
2. The Urology Foundation (UK)
3. National Institute for Health and Care Research (UK)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309977

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54815, IRAS 309977

Study information

Scientific Title
Memokath 051 Double cone metallic stents in treating intractable ureteric obstruction

Acronym
MinUS

Study objectives
The Memokath 051 Double cone metallic stent improves quality of life and reduces the need for stent change and hospital visits compared to standard care (JJ stent). It does not cause the stent-related symptoms caused by the JJ stent.

This study aims to observe the improvement in quality of life with Memokath compared to the JJ Stent and the longevity of the Memokath for over 2 years. The researchers will use validated questionnaires to assess the patient's stent symptoms and quality of life with the JJ in place and after the Memokath is inserted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2023, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, Health Research Authority, BS1 6PN, UK; +44 (0)207 1048106; frenchay.rec@hra.nhs.uk), ref: 22/SW/0175

Study design
Non-randomized; Both; Design type: Treatment, Process of Care, Device, Complex Intervention, Surgery, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intractable ureteric obstruction

Interventions
Potentially eligible patients will be approached before the stent surgery is due to take place, either during routine clinic visits and /or by sending a study invite letter. At this point, a copy of the patient information sheet will be given to them. This will happen at least a week in advance. They will also be informed about the standard care that will be in place in the event of failure of the Memokath or withdrawal from the study at any point.

If the patient meets the eligibility criteria and agrees to take part in the study, they will be asked to sign for consent. At this stage the participant enters the preliminary recruitment stage and is asked to complete a urology stent symptom questionnaire and quality of life questionnaire (EQ-5D). The patient is then listed for Memokath insertion.

After successful insertion of the Memokath stent, the patient enters the final recruitment stage.

There will be follow-up visits at 3, 6, 12, 18 and 24 months post-insertion, including clinical assessments, blood investigations, Kidneys, Ureters, and Bladder (KUB) X-ray and MAG-3 isotope renogram and questionnaires.

If Memokath insertion fails and participants have insertion of a JJ stent or alternative, they will continue to undergo follow-up, as Memokath participants will do (except X-ray KUB and MAG-3) till the end of the study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Quality of life is measured using EQ-5D on two occasions 3 months apart with JJ stent in situ, and after Memokath insertion at 3, 6, 12, 18 and 24 months

Secondary outcome measures
1. Stent-related symptoms are measured using the validated Urology Stent Symptom Questionnaire (USSQ) on two occasions 3 months apart with JJ stent in situ, and after Memokath insertion at 3, 6, 12, 18 and 24 months.
2. Renal function preservation is measured using estimated glomerular filtration rate (eGFR) and

nuclear medicine scan once with JJ stent in situ. After Memokath insertion eGFR is checked at 3, 6, 12, 18 and 24 months. Nuclear medicine scan is performed at 3, 12 and 24 months.
3. Cost-effectiveness measured using NHS resource use data capture on two occasions 3 months apart with JJ stent in situ, and after Memokath insertion at 3, 6, 12, 18 and 24 months.
4. The longevity of Memokath is measured by observing the function and drainage of the renal units after Memokath insertion by eGFR and X-ray KUB at 3, 6, 12, 18 and 24 months. Nuclear medicine scan is performed at 3, 12 and 24 months.

Overall study start date
04/06/2021

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Dependent on JJ stent for management of unilateral or bilateral ureteric obstruction
2. Benign or malignant obstruction
3. Life expectancy of more than 2 years
4. Renal unit function of more than 20, as assessed by nuclear medicine scan
5. Normal ureter below and above the level of obstruction as observed by retrograde pyelogram or ureteroscopy
6. Stricture not suitable or patient unfit for reconstructive surgery (OR patient choice as documented in clinic letter or medical notes)
7. Fit to undergo retrograde MK-051 insertion under general or regional anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
1. Age less than 18 years
2. Allergy to nickel
3. Renal unit function less than 20, as assessed by nuclear medicine scan
4. Pelvic ureteric junction (PUJ) involved in stricture
5. Vesico-ureteric junction (VUJ) involved in stricture
6. Primary PUJ obstruction or Mega Ureter
7. Not on JJ stent

8. Life expectancy less than 2 years
9. Previous active stone (stones present in the kidney, metabolic stone disease, forming stones within 2 years before recruitment)
10. Disease that requires ureteric instrumentation for treatment
11. Lack of capacity

Date of first enrolment
01/04/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
Rochdale Infirmary
Whitehall Street
Rochdale
United Kingdom
OL12 0NB

Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital

Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Queens Hospital
Rom Valley Way
Romford
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RM7 0AG

Study participating centre
King George Hospital
Barley Lane
Goodmayes
Ilford
United Kingdom
IG3 8YB

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

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TS4 3BW
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Sponsor type
Hospital/treatment centre

Website
http://southtees.nhs.uk/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Charity

Funder Name
Urology Foundation

Funder Name
PNN Medical A/S

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date