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Memokath Prostatic Stent Study

Submission date
11/04/2012

Recruitment status
No longer recruiting

Registration date
11/04/2012

Overall study status
Completed

Last Edited
24/01/2018

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims:
Urine retention is a condition in which a man is unable to empty his bladder in the normal way, usually due to an enlarged prostate (an 'O'-shaped gland which surrounds the tube that takes urine from the bladder to the penis, and is situated just below the bladder). There are several different options for treating this condition (including surgery), but not all of these are always suitable.
The most widely used treatment is a long-term catheter. This is a plastic tube inserted into the penis, through the urethra to the bladder. It collects urine in a plastic bag attached to the leg. These work well in most people, but do need changing every few weeks. They can be inserted, usually at home, by a community nurse and an operation is not needed.
Another option, which is not very widely used in the UK at present, is for the man to have a prostatic stent fitted inside the urethra where it passes through the prostate. The stent is a metal coil, like a Biro spring, which is inserted into the urethra where it passes through the prostate. Once in position, it expands and prevents the prostate from squeezing the urethra shut. The stent is fitted in the operating theatre in a 10-15 minute procedure using a flexible telescope, under a local anaesthetic. About 4 out of 5 men who have this done can pass urine normally afterwards.
We want to compare the quality of life of men having these two treatments, so that in the future we can advise men which is the better option for them.

Who can participate?
Men who have urinary retention due to an enlarged prostate, who are being treated with a long-term catheter and are not suitable for surgery. They must otherwise be fit and well.

What does the study involve?
If a patient decides to take part they will be allocated to either continue their treatment with the long-term catheter or to have a prostatic stent. A computer will be used to ensure that the treatment option allocated to the patient is decided by chance, like tossing a coin. This means that neither the patient nor the trial doctor will be able to choose which treatment is received whilst participating in the study. If the patient receives a prostatic stent, a hospital appointment will be made so the stent can be put in place. This will usually be within about two weeks of signing the consent form.
Each person takes part in the trial for 6 months. They will be asked to come to the hospital 3 months after they have started the trial, and again at 6 months. At these visits they will be asked

to fill in some questionnaires about their general health and wellbeing, urinary retention symptoms, and how they have found taking part in the trial.
At the end of the study, each participant can choose whether they would like to be treated with a stent or a long-term catheter, regardless of which treatment they had during the trial.

What are the possible benefits and risks of participating?
Patients might benefit from receiving the stent, which currently is not widely available in the UK. However, even if they are allocated to continue with your long-term catheter, they might feel benefit from having increased access to a medical team. Some people also like taking part in research because they feel that they are helping other patients like themselves in the future.
There are side effects associated with both of the treatment options. Long-term catheters work well in most men, but some find them uncomfortable. Catheters also require some upkeep as they need changing every few weeks, and can become blocked. They can cause a bit of blood in the urine, urine infections and bladder stones. When a person has a long term catheter fitted, the clinician will usually tell them what to do if they have any problems with it.
Prostatic stents can sometimes, particularly in the early stages, cause problems such as leakage of urine, needing to pass urine frequently, bleeding into the urine, urine infections or retention of urine. Occasionally, the stent can move up into the bladder or move down into the urethra.

Where is the study run from?
Wonford Hospital, which is part of the Royal Devon and Exeter NHS Foundation Trust. All study visits will take place at the Wonford Hospital in Exeter.

When is study starting and how long is it expected to run for?
From November 2011 until October 2012

Who is funding the study?
National Institute of Health Research (NIHR) Research for Patient Benefit Scheme

Who is the main contact?
Linda Park (Research Nurse)
Wonford Hospital
01392 408935

Contact information

Type(s)
Scientific

Contact name
Mr Christopher Hayward

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11340

Study information

Scientific Title
Pilot investigation of the effect of the Memokath 028 Prostate® stent on quality of life in patients with urethral obstruction a comparison with long term catheter

Acronym
MePSS

Study objectives
Aim of this pilot trial is to investigate the effect of the Memokath 028 Prostate® stent on quality of life in patients with urethral obstruction a comparison with long term catheter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West Cornwall and Plymouth, 07/11/2011, ref: 11/SW/0194

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Renal surgery

Interventions
This pilot trial will recruit 60 men with retention of urine, and these will be randomised in a 1:1 ratio to either continue with the long term catheter that they already have fitted or to have a prostatic stent fitted. Participants will be followed up by telephone at two weeks, and at outpatient visits at 3 and 6 months. At these timepoints, men will provide information on their general health and well-being, on any problems they have experienced with their catheters /stent and whether or not they have had to see the doctor or community nurse. Three questionnaires relating to quality of life will be used as the primary outcome measure and will be completed by participants at the beginning of the study, at the three month visit and finally at the 6 month visit. The pilot trial will be conducted at a single site - the Royal Devon and Exeter hospital

MemokathTM 028 Prostatic Stent, Treatment of urinary retention with the insertion of a MemokathTM 028 Prostatic Stent, in comparision with current standard treatment of Long Term Catheter.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Health Related Quality of Life measured using:
1. SF-36 at baseline, 3 months and 6 months
2. ICIQ-MLUTS at baseline, 3 months and 6 months
3. ICIQ-LUTSqol at baseline, 3 months and 6 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/11/2011

Completion date
15/09/2012

Eligibility

Key inclusion criteria
1. Men aged 50 years and older
2. Acute or chronic urinary retention initially treated with a urethral catheter
3. Considered to be medically unfit for, or to present a significant risk for TURP, such that the admitting urologist would consider a long term catheter to be the standard management.

4. Considered by the admitting urologist and trial team to be medically suitable to be managed with a long term prostatic stent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Inability or unwillingness to sign informed consent form / any written questionnaire and participate in investigation due to physical or mental limitations
2. Meatal or urethral strictures that cannot be opened to 26 Fr
3. Urethral diverticuli
4. Any known condition requiring transurethral manipulations within 6 months after stent placement
5. Bladder stones, bladder or urethral carcinoma
6. Prior TURP or other surgical intervention for BPH within the last year
7. Presence of another urological prosthesis
8. Unresolved major symptomatic medical problem which would interfere with the investigation, including any and all disorders contraindicating insertion and/or removal procedure
9. Life expectancy < 1 year
10. Concurrent participation in another clinical trial during the period of this investigation

Date of first enrolment
15/11/2011

Date of final enrolment
15/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Plymouth Hospital NHS Trust
Plymouth
United Kingdom
PL6 8BX

Sponsor information

Organisation
Royal Devon and Exeter Foundation Trust (UK)

Sponsor details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration