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Comparison of standard JJ stents to magnetic JJ stents with regard to stent placement and removal discomfort and cost analysis

Submission date
15/01/2021

Recruitment status
Stopped

Registration date
22/01/2021

Overall study status
Stopped

Last Edited
16/10/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
For over 40 years ureteric stents have been used in urology and the placement of a ureteral stent is the most frequent urological intervention performed. Modern ureteric stents are thin, flexible plastic tubes which are curled at both ends to avoid damaging the kidney and urinary bladder and to prevent it from dislocating.
There are certain reasons for stent placement, for example after kidney stone removal. Unfortunately up to 80% of patients complain about irritative voiding (urinating) symptoms after stent implantation. Usually, the stent is removed after 714 days. The standard procedure to remove a stent is by cystoscopy.
The cystoscopic removal of stents can be unpleasant and needs specific preparation for up to 30 minutes. The idea to remove a stent by using two magnets has been tried to be implemented for over 10 years and only recently have magnetic stents been available. Despite the wide adoption of magnetic stents worldwide, there is a relative lack of data to support their use compared to non-magnetic stents.
The aim of this study is to assess the effectiveness of a magnetic stent that allows for removal without cystoscopy. The impact on patient's quality of life in terms of stent and stent removal related symptoms, as well as the stent removal, will especially be addressed.

Who can participate?
All patients who had a short term (<6 weeks) stent placed, either magnetic or conventional

What does the study involve?
When it is time to place a stent at the end of a ureteroscopy procedure, participants are randomly allocated to have either a magnetic stent or a conventional ureteric stent placed. When the patients return to have their stent removed, they will undergo a quality of life assessment with a symptom questionnaire. After the stent is removed, the discomfort caused by the removal is recorded. Patients will be followed up for a minimum of 6 months.

What are the possible benefits and risks of participating?
There is no direct benefit to participants. However, there is a benefit to society, as participating

in this study will increase knowledge about which type of stent is more comfortable for patients and which removal method is least painful. Participants may require a stent regardless of being in the study. Both types of stents are commonly used already and participating in this study has no risk.

Where is the study run from?
Mercy University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
July 2020 to February 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Derek Hennessey
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
ECM 4 (c) 07/07/2020

Study information

Scientific Title
A prospective single-centre randomised control trial of magnetic DJ stents versus conventional DJ stents

Study objectives
That magnetic DJ stents are superior to conventional DJ stents with regard to removal discomfort and cost.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/09/2020, Clinical Research Ethics Committee Of the Cork Teaching Hospitals (Lancaster Hall, 6 Little Hanover Street, Cork, Ireland; +353 (0)21 4901901; crec@ucc.ie), ref: ECM 4 (c) 07/07/2020, ECM 3 (z) 20/10/2020

Primary study design
Interventional

Study design
Prospective randomized control trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post ureteroscopy renal drainage with a DJ stent

Interventions
When it is time to place a ureteric stent at the end of a ureteroscopy procedure, a random number generator will be used to generate a number. When an even number is generated, a magnetic ureteric stent will be placed, and an odd number meaning a conventional ureteric stent will be placed. When the patients return to have their stent removed, they will undergo a quality of life assessment with a ureteral symptom questionnaire (USSQ). After the stent is removed, a visual analogue scale (VAS) will be used to document the discomfort caused by the D Jremoval. Patients will be followed up for a minimum of 6 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Quality of life assessed using ureteral symptom questionnaire (USSQ) immediately prior to JJ stent removal
2. Stent removal pain assessed using a visual analogue scale (VAS) after JJ stent removal

Key secondary outcome(s)
Cost of each type of stent, including removal, measured using Total Resource Use Index after data collection is complete

Completion date
02/02/2024

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria

All patients who had a short term (<6 weeks) JJ stent placed, either magnetic or conventional

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients aged under 18 years
2. Pregnant women
3. Sheltered patients
4. Patients taking alpha-blockers or anticholinergics

Date of first enrolment
01/10/2020

Date of final enrolment
02/02/2024

Locations

Countries of recruitment
Ireland

Study participating centre
Mercy University Hospital
Grenville Place
Cork
Ireland
T12 WE28

Sponsor information

Organisation
Mercy University Hospital

ROR
https://ror.org/017q2rt66

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/02/2021	No	Yes
Protocol file			04/02/2021	No	No