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A prospective randomised controlled trial comparing two ureteric stents (CE marked) using a validated quality of life (HRQoL) questionnaire

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
28/07/2008

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0234175450

Study information

Scientific Title

Study objectives
To study and compare the effect of 2 different indwelling ureteric stents on patients symptoms and quality of life. Ureteric stents need to be stuff enough for east of insertion and soft enough for increased comfort whilst in situ. Previous studies have shown that ureteric stents cause side effects in the majority of patients. We aim to assess the difference between side effects with the present stent compared to a newer developed stent. The main objective is to see whether either stent is superior with regard to the frequency and severity of side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 28 July 2008:
Granted by North Bristol NHS Trust Research Ethics Committee.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Urological and Genital Diseases:

Interventions
Informed written consent will be obtained from 100 prospective patients. Pre stent symptom questionnaire will be completed pre-procedure. Each patient will be randomised to receive either the Bard Inlay stent of the Microvasice Polaris stent. The type of stent used will be blinded from the patient and the researcher recording information. Once the stent has been

indwelling for one week, the stent in situ questionnaire will be completed. Following removal of the stent the post stent questionnaire will be completed. On completion of the questionnaires, comparative scores from the 2 groups will undergo statistical analysis.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Added 28 July 2008:
Compare health related QOL (using the USSQ) between the two groups at 2 weeks post insertion of stent

Secondary outcome measures
Added 28 July 2008:
Difference in GP and hospital visits, UTI and antibiotic use between two groups with stent in situ

Overall study start date
01/01/2002

Completion date
01/02/2006

Eligibility

Key inclusion criteria
Added 28 July 2008:
Patients (aged 16 yrs or over) requiring the placement of a ureteric stent for stone disease, including obstructing ureteric stones, large stones prior to lithotripsy or post ureteroscopy plus or minus stone fragmentation.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Added 28 July 2008:
Those with pelvi-ureteric junction obstruction, upper tract malignancy, indwelling stent, concurrent urinary tract infection, pregnancy, bilateral instrumentation or aged less than 16 yrs of age

Date of first enrolment
01/01/2002

Date of final enrolment
01/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lithotripsy Unit
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust (UK) NHS R&D Support Funding (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/03/2008		No	No