

# 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

☒ Results

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 stiff enough for ease 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 or 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

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SW1A 2NL

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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?
<a href="#">Abstract results</a>		01/03/2008		No	No