Supine versus Prone Extracorporeal Shockwave Lithotripsy for Proximal Ureteric Stones

Submission date	Recruitment status	Prospectively registered
28/09/2007	Stopped	[_] Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Stopped	[_] Results
Last Edited	Condition category Urological and Genital Diseases	Individual participant data
05/04/2012		[_] Record updated in last year

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 N0234179134

Study information

Scientific Title

Study objectives

We are looking at the effect patient position has on the success of lithotripsy for stones located in the upper ureter. Upper ureteric stones may be treated with the patient lying on his/her back or front. We aim to determine whether one position is more effective at breaking the stone than the other.

As of 05/04/2012, the anticipated end date of trial has been updated from 01/08/2008 to 01/08 /2007.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled 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

Urological and Genital Diseases: Calculus of ureter

Interventions

All patients presenting for lithotripsy to an upper ureteric stone will be approached immediately prior to treatment regarding inclusion. A full explanation of the treatment and study protocol will be given and the patients will be given the opportunity to ask questions and consult family members. Those in agreement to participate will be asked to sign a consent form. The position for treatment will be allocated immediately prior to treatment using sealed envelopes. All patients will receive a maximum of 3000 shockwaves at a maximum power of 100%. Following each treatment patients will be asked to complete a short patient satisfaction questionnaire, including a pain score.

Patients will be reviewed at the time of their second treatment two weeks later with a KUB x-ray (standard practice). The presence, site and size of any residual stone will be recorded. The second treatment will also be given in the same position as the first. Any patients requiring a

second treatment will be reviewed in an outpatient clinic 2 weeks later to determine the outcome, again using a KUB x-ray (standard practice).

Sample size - a sample of 182 patients (91 patients in each group) would enable the detection of a standardised difference in SWL success rates of 20% or greater when patients are treated prone versus supine. This estimate was based on a two-tailed, paired t-test, using 80% power and a 5% significance level.

Study End Point - the study will be discontinued once either the stone has been confirmed to have passed using x-ray KUB or persistent stone presence following two consecutive treatments.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

1. Proximal ureteric stone passage rates at 2 weeks following first SWL treatment

2. Proximal ureteric stone passage rates at 2 weeks following second SWL treatment

Secondary outcome measures

1. Total time taken to perform treatment (time from first screening to discontinuation of shock wave delivery)

2. Power and number of shocks delivered per treatment

3. PCA (patient controlled analgesia) use

4. Complication rates and the number of ancillary procedures required in each group

Overall study start date

19/04/2006

Completion date

01/08/2007

Reason abandoned (if study stopped)

"Participant recruitment issue"

Eligibility

Key inclusion criteria

Any patient with a proximal ureteric stone (all stones located proximal to the sacroiliac joint) will be considered for inclusion.

Participant type(s) Patient

Age group Not Specified Not Specified

Target number of participants 182 patients (91 patients in each group)

Key exclusion criteria
1. Ureteric stent or nephrostomy in situ
2. Radiolucent stone
3. Any patient unable to lie supine or prone for any reason
4. < 16 years old

Date of first enrolment 19/04/2006

Date of final enrolment 01/08/2007

Locations

Countries of recruitment England

United Kingdom

Study participating centre Bristol Urological Institute Bristol United Kingdom BS10 5NB

Sponsor information

Organisation Record Provided by the NHSTCT Register - 2007 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

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