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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**	[_] Individual participant data
05/04/2012	Urological and Genital Diseases	[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration