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A randomised clinical trial to evaluate the effect of reducing the shock wave frequency during shock wave lithotripsy for renal calculi

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/07/2008	Urological and Genital Diseases	

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
N0234166115

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Consecutive patients with renal calculi attending for lithotripsy will be randomised to receive treatment at either 60 or 120 shock waves per minute. The shock wave lithotripsy treatment will be given using the current protocols, with patient care being altered in no other way. Patients will be reviewed after 3 months with a KUB X-ray, and retreated to a maximum of three treatments if there are remaining fragments greater than 4mm.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2002

Completion date
01/08/2005

Eligibility

Key inclusion criteria
100 adults

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2002

Date of final enrolment
01/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Sponsor information

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

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

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?

Results article	results	01/11/2006	Yes	No