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Influence of the frequency of shock waves on the effectiveness of extracorporeal shock wave lithotripsy in distal ureteral calculi

Submission date	Recruitment status	[_] Prospectively registered
11/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/06/2010	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A randomised single-blind study to assess if a decreased shock wave frequency implements the efficacy of fragmentation rate in distal ureteral calculi

Study objectives
Extracorporeal lithotripsy devices apply treatment in a wide range of frequencies. Several studies in animals and humans have shown that the fragmentation is greater with decreasing frequency, in the lithiasis located in kidney and/or proximal urether. This study aims to demonstrate that the application of lithotripsy in distal ureter is more efficient at 60 beats per minute, compared with treatments applied at 80 pulses per minute.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Universitary Hospital Reina Sofia Ethics Board approved in July 2008

Study design
Randomised single-blind single centre study

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
Ureteral lithiasis

Interventions
Higher frequencies are often used in lithotripsy because they consume less time. Lithotripsy is performed in this study within the specifications allowed by the equipment. Patients are randomised into two arms:
1. Patients receive lithotripsy at 60 beats per minute
2. Patients receive lithotripsy at 80 beats per minute

In the two treatment arms pethidine is used as analgesic. The maximum duration of each session is fifty minutes. The maximum number of sessions is three. The estimated maximum follow-up is for three months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pethidine

Primary outcome measure
Number of pulses required for treatment success, measured at the end of follow-up.

Secondary outcome measures
1. Days to total expulsion of fragments: days required from first session to total elimination of stones, measured at the end of follow-up
2. Total number of sessions required: one to three, measured at the end of the follow-up
3. Success rate, measured at the end of the follow-up

Overall study start date
01/09/2008

Completion date
15/01/2010

Eligibility

Key inclusion criteria
1. Patients with ureteral radiopaque lithiasis subsidiary of lithotripsy treatment
2. Aged greater than 18 years, either sex
3. Lithiasis located in distal ureter
4. Lithiasis size greater than 0.5 cm and less than 1 cm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
154 patient, 77 in each arm

Key exclusion criteria
1. Aged less than 18 years
2. Medical contraindication for lithotripsy
3. Lithiasis less than 0.5 cm and greater than 1 cm
4. Other localisation than distal ureter
5. Indwelling ureteral catheter
6. Nephrostomy catheter
7. Severe hydronephrosis with kidney function impairment

Date of first enrolment
01/09/2008

Date of final enrolment
15/01/2010

Locations

Countries of recruitment
Spain

Study participating centre
Av Menendez Pidal sn
Cordoba
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14011

Sponsor information

Organisation
Association of Urology Research and Development (Asociacion de Urologia y Desarrollo de la Investigacion) (Spain)

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Sponsor type
Research organisation

ROR
https://ror.org/039xbga15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Reina Sofia Universitary Hospital (Spain) - Urology Unit

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