

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

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Registration date 07/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/06/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Spain

14011

Sponsor information

Organisation

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

ROR

<https://ror.org/039xbga15>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Reina Sofia Universitary Hospital (Spain) - Urology Unit

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration