ISRCTN98702137 https://doi.org/10.1186/ISRCTN98702137

Antioxidant therapy in implementing lithotripsy in patients with renal lithiasis

Submission date	Recruitment status	[_] Prospectively registered
14/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/03/2010	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
Randomised, prospective double-blind, placebo-controlled study to evaluate the effect of antioxidant therapy in preventing kidney damage caused by lithotripsy

Study objectives
The initial treatment in most cases of urolithiasis is actually the application of extracorporeal shockwave lithotripsy. However, pressure waves cause damage to the renal parenchyma. The mechanism of tissue damage is not well known. The collapse of cavitation bubbles generated by the waves may be responsible of the cellular changes, facilitated by the formation of small collections after the rupture of microvessels. There are underlying hormonal vasoactive inflammatory phenomena. The final common mediator lies in oxidative imbalance, with increased lipid peroxidation and decrease of cellular antioxidant capacity.
The aim of the trial is to assess if the association of a drug with a potent antioxidant effect, alpha lipoic acid (ALA), avoids or diminishes the renal injury caused by lithotripsy.
Secondary objectives are:
1. Evaluate changes in markers of renal damage and function after application of the shockwaves.
2. Determine the status of parameters of oxidative stress markers and antioxidant defenses and any changes after treatment with lithotripsy.
3. Assess the state of vasoactive hormones involved in pathogenesis of renal injury associated with kidney stones, and the application of lithotripsy.
4. Analyze the impact of the administration of ALA in parameters of oxidative stress parameters, hormonal and renal damage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trial approved by Local Reina Sofia Hospital Clinical Trials Committee on February 25th, 2009 (acta: 168; ref: 1483)

Study design
Single centre interventional prospective double blind two arm randomised placebo controlled parallel group 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 contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Kidney stone disease treated by extracorporeal shockwave lithotripsy

Interventions
There are two arms, the treatment arm will receive alpha lipoic acid and the other one placebo. After being assigned by a randomisation program, obtained from the web page www. randomization.com, the patients included in the treatment arm will receive ALA (400 mg/day), those assigned to the placebo arm will receive a placebo of identical dosage and appearance. Both drug and placebo will be presented in oral pills, distributed in two jars, containing a week of pills in each. Patients will take one pill twice daily for a total of two weeks.

The total duration of the follow-up period is two weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Alpha lipoic acid (ALA)

Primary outcome measure
1. Renal vascular resistance index (ipsilateral and contralateral peripheric), measured by Doppler ultrasound of an interlobar artery branch at baseline, 24 hours and 10 days after lithotripsy.
2. Laboratory measurements, calculated from blood and urine samples taken at baseline, 2 hours before, 1 hour, 24 hours and 10 days after lithotripsy:
2.1. Lipoperoxides (MDA-4HA) (nmol/g)
2.2. Reduced Glutathione (GSH) (micromol/g)
2.3. Catalase
2.4. Superoxide dismutase
2.5. Gluthatione peroxidise
2.6. DNA damage (8OHdG)
2.7. Serum Nitric Oxide (NO) (nM/mL)
2.8. Renin (pg/ml)
2.8. Kallikrein
2.9. Serum aldosterone (ng/dl)
2.10. Endothelin-1 (pg/ml)
2.11. Urine Prostaglandin E2 (PGE2)
2.12. alpha Tumour Necrosis Factor (αTNF)
2.13. 1beta-Interleukin (IL)
2.14. 6-IL

Secondary outcome measures
Determination of glomerular filtration:
1. Cockroft-Gault
2. Modification of Diet in Renal Disease (MDRD)
3. Fractional excretion of sodium (mEq/l)
4. Corrected hyperglycemia Sodium (mEq/l)
5. Plasma osmolarity (mOsm/kg)
6. Blood Urea Nitrogen (BUN) (mg/100 ml)

7. B2 microglobulin (microg/min)
8. Albumin (g/l) in urine
9. Adrenomedullin
10. Lactate dehydrogenase (LDH) (units)
11. N-acetyl-D-glucosaminidase (NAG) (IU/l)
12. Alanine aminopeptidase (AAP) (IU/l)
13. Aspartate aminotransferase (AST)
14. Alanine aminotransferase (ALT)
15. Gammaglutamiltranspepsidasa (GGT)
16. Leucine aminopeptidase (LAP)
17. B-galactosidase

Overall study start date
01/04/2009

Completion date
01/10/2010

Eligibility

Key inclusion criteria
Patients > 18 yr with renal stones scheduled to be treated by extracorporeal shockwave lithotripsy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Target sample size of 126 patients, 63 in each group.

Key exclusion criteria
1. Any contraindication for lithotripsy.
2. Patients undergoing lithotripsy at the time of initiating the study
3. Severe impairment of treated kidney
4. Complications related to lithotripsy that need of an interventional procedure during the study period
5. Inability to understand or psychosocial maladjustment
6. Refusal to sign the informed consent form

Date of first enrolment
01/04/2009

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Spain

Study participating centre
Arroyo del Moro 6
Cordoba
Spain
14011

Sponsor information

Organisation
Reina Sofia Universitary Hospital (Spain)

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Sponsor type
Hospital/treatment centre

Website
http://www.hospitalreinasofia.org

ROR
https://ror.org/02vtd2q19

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Reina Sofia University Hospital (Spain)

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