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Coenzyme Q10 therapy in lithotripsy in patients with renal lithiasis

Submission date	Recruitment status	[_] Prospectively registered
20/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/03/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/03/2010	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

Contact name
Dr Julia Carrasco

Contact details
Hu Reina Sofia
Servico de Urologia
3ª Planta Edificio de Consultas
Avda Menendez Pidal S/N
Cordoba
Spain
14004
+34 629 80 37 51
juliacv83@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Coenzyme Q10 therapy in lithotripsy in patients with renal lithiasis: a prospective randomised double-blind trial

Acronym
Q10LT

Study objectives
Urinary tract lithiasis is associated with renal damage secondary to the appearance of inflammatory changes and imbalances in hormone regulation of angiotensin II axis, which finally lead to the development of fibrosis. Today it is accepted that the treatment of initial choice for most cases of urolithiasis is the application of extracorporeal shockwave lithotripsy that by shock wave emission causes fragmentation of the calculus, allowing their elimination by the excretory way. Associated to the injuries by lithotripsy appears inflammatory phenomena and vasoactive hormonal. In both cases, the final common mediator lies in oxidative imbalance.

Therefore, the use of drugs with antioxidant capacity, such as co-Q10 might reduce kidney damage associated with the application of lithotripsy for patients with urinary tract lithiasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of the Reina Sofia Hospital approved in February 2009

Study design
Prospective randomised controlled double-blind trial

Primary study design
Interventional

Secondary study design
Non 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
Renal lithiasis

Interventions

Coenzyme Q10 is administered (two 30 mg capsules every 8 hours) for 14 days versus placebo.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Coenzyme Q10

Primary outcome measure
Determination of glomerular filtration rate (MDRD), measured in June 2010 and September 2010

Secondary outcome measures
Measured in June 2010 and September 2010:
1. Biochemical markers of oxidative stress:
1.1. MDA
1.2. Glutation
1.3. SOD
1.4. Catalase

Overall study start date
01/05/2009

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Adult patients aged 25 to 65 years (either sex) with urinary tract lithiasis
2. Candidates to applying lithotripsy
3. Lithiasis located in the renal pelvis and/or calyx

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A total of 112 patients (56 in each group)

Key exclusion criteria
1. Patients undergoing lithotripsy at the time of initiating the study
2. Patients with previously diagnosed renal lithotripsy

3. Patients treated with calcium channel blockers
4. Complications of lithotripsy that determine the need for further intervention in the study period
5. Taking antiplatelet 3 days before extracorporeal shock-wave lithotripsy (ESWL) session
6. Controlled clotting disorders
7. Complete distal obstruction to the calculation to be treated
8. Unrecovery kidney
9. Allergy to the components of medications
10. Inability to understand or psychosocial misadjustment
11. Refusal to sign informed consent

Date of first enrolment
01/05/2009

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Spain

Study participating centre
Hu Reina Sofia
Cordoba
Spain
14004

Sponsor information

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

Sponsor details
Hu Reina Sofia
Servico de Urologia
3ª Planta Edifico de Consultas
Cordoba
Spain
14004
+34 629 80 37 51
juliacv83@hotmail.com

Sponsor type

Research organisation

ROR
https://ror.org/039xbga15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hu Reina Sofia 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