# 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	<ul><li>Record updated in last year</li></ul>

### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# 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

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# 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