

# Effects of aminobisphosphonates and thiazides in patients with osteopenia / osteoporosis, hypercalciuria and recurring renal calcium lithiasis

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/04/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Kidney stones (renal calcium lithiasis) form if there's too much calcium in the urine (hypercalciuria), and can block the urinary system and cause severe pain. Osteopenia /osteoporosis are conditions where bone density is decreased, making them fragile and more likely to break. The aim of this study is to assess the effects of a combination of drugs (alendronate and hydrochlorothiazide) on patients with renal calcium lithiasis, hypercalciuria and osteopenia/osteoporosis .

### Who can participate?

Patients aged between 25 and 60 with renal calcium lithiasis, hypercalciuria and osteopenia /osteoporosis

### What does the study involve?

Participants are treated with either alendronate or alendronate and hydrochlorothiazide for 3 years. At the start of the study each participant's medical history is taken, a physical examination is performed and the participant's weight, height and blood pressure are measured. X-ray and/or ultrasound scans are performed to check for kidney stones at the start of the study and every 6 months. Blood and urine samples are taken at the start of the study and after 6 months and 2 years. Bone mineral density is assessed at the start of the study and after 2 years of treatment using a DEXA scan (a type of x-ray). Side effects are measured every 6 months.

### What are the possible benefits and risks of participating?

The possible benefits of the study are improvement of bone mineral density and stabilization of kidney stone disease. The risks are those arising from the side effects of the drugs such as low blood pressure, electrolyte (blood salt level) disturbances or esophagitis (inflammation of the gullet), which occur in a very low number of patients.

Where is the study run from?  
San Cecilio University Hospital (Spain)

When is the study starting and how long is it expected to run for?  
June 2005 to June 2008

Who is funding the study?  
San Cecilio University Hospital (Spain)

Who is the main contact?  
Dr Miguel Angel Arrabal-Polo  
arrabalp@ono.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Miguel Angel Arrabal-Polo

**Contact details**  
Camino de Ronda street 143  
Granada  
Spain  
18003  
-  
arrabalp@ono.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Effects of aminobisphosphonates and thiazides in patients with osteopenia/osteoporosis, hypercalciuria and recurring renal calcium lithiasis: an observational study

**Study objectives**  
The effect of alendronate in bone mineral density loss and calcium stones is increased when we add thiazides and we will obtain a better response than patients only treated with alendronate.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of the University Hospital San Cecilio of Granada, January 2005

**Study design**

Observational study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Bone mineral density loss and renal calcium stones

**Interventions**

The patients were divided into two groups:

Group 1 included 35 patients between 25-60 years of age diagnosed with renal calcium lithiasis (moderate or severe lithiasic disease), hypercalciuria and loss of bone mineral density. Patients in this group were treated for three years with alendronate sodium (70 mg/week)

Group 2 included 35 patients between 25-60 years of age diagnosed with renal calcium lithiasis (moderate or severe lithiasic disease), hypercalciuria and loss of bone mineral density; patients in this group were treated for three years with alendronate sodium (70 mg/week) and hydrochlorothiazide (50 mg/day).

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Alendronate sodium, hydrochlorothiazide

**Primary outcome measure**

1. Each patient's medical history is taken, a physical examination is performed and the patient's weight, height, body mass index and blood pressure are measured and recorded
2. Abdominal radiography and intravenous urography and/or ultrasound performed at the outset of the study to evaluate the presence or absence of calcium lithiasis and the size of lithiasic residues before medical treatment begins
3. Analysis of calculi performed in all cases
4. Blood and urine biochemistries performed at baseline and at six months and two years
5. Plasma levels of the following variables: glucose, creatinine, urea, uric acid, sodium, potassium, chloride, calcium, phosphorus, alkaline phosphatase, intact parathyroid hormone (iPTH), osteocalcin, beta-crosslaps, beta-crosslaps/osteocalcin and vitamin 1-25 OH-D. The 24-hour urine study included diuresis, creatinine clearance, creatinine, calcium, phosphorus, uric acid, oxalate, citrate, magnesium and the calcium/citrate ratio

### **Secondary outcome measures**

1. Bone mineral density, measured at baseline and at two years of treatment. Bone densitometry was performed by dual-energy x-ray absorptiometry using a Hologic QDR 4500. At the onset of the study, patients were classified as calcium lithiasic formers with moderate or severe lithiasic disease based on the changes that had occurred over the previous three years
2. Growth of residual lithiasis and relapsing lithiasis, measured by means of an ordinary X-ray of the urinary system performed every six months. At the end of the three-year study, the degree of relapse was determined as well as whether there had been lithiasic growth or decrease due to spontaneous excretion present at the onset of treatment
3. Side effects, measured every six months

### **Overall study start date**

01/06/2005

### **Completion date**

01/06/2008

## **Eligibility**

### **Key inclusion criteria**

Men and women 25-60 years of age with moderate or severe lithiasic disease and bone mineral density loss

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

70

### **Key exclusion criteria**

1. Patients > 60 or <25 years
2. Patients with congenital bone disease
3. Congenital renal disease
4. Hyperparathyroidism
5. Inflammatory bowel disease or renal tubular acidosis and
6. Patients undergoing hormone replacement therapy or treatment with corticosteroids, calcium and/or vitamin D

**Date of first enrolment**

01/06/2005

**Date of final enrolment**

01/06/2008

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

Camino de Ronda street 143

Granada

Spain

18003

## **Sponsor information**

**Organisation**

San Cecilio University Hospital (Spain)

**Sponsor details**

Avenida Doctor Oloriz

Granada

Spain

18012

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/02pnm9721>

# **Funder(s)**

## **Funder type**

Hospital/treatment centre

## **Funder Name**

San Cecilio 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