ISRCTN70158709 https://doi.org/10.1186/ISRCTN70158709

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

Submission date
25/04/2012

Recruitment status
No longer recruiting

Registration date
04/05/2012

Overall study status
Completed

Last Edited
25/04/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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