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Calcium supplements for the prevention of osteoporosis in perimenopausal women

Submission date
15/01/2019

Recruitment status
No longer recruiting

Registration date
07/03/2019

Overall study status
Completed

Last Edited
08/03/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis is a bone disease that occurs when the body loses too much bone, makes too little bone, or both. As a result, bones become weak and may break from a fall.

Frequently, calcium supplements are recommended for the prevention or the treatment of the osteoporosis.

The main objective of the present study is to confirm whether the treatment with the ossein-hydroxyapatite complex, a calcium supplement, is better tolerated than the treatment with calcium carbonate, another calcium supplement.

Who can participate?
Women in the perimenopausal period.

Perimenopause takes place over several years in advance of the menopause and can last for 4 to 8 years. Thus, women between 40 and 50 years that are in the perimenopausal period, according to their physicians, are included in the study.

Women with normal bone density or slightly reduced (what is called osteopenia) are included in the study.

What does the study involve?
As the study compares two different calcium supplements, a group of participants is treated with 2 tablets every 12 hours of ossein-hydroxyapatite complex, a calcium supplement, and the other with 1 tablet every 12 hours of calcium carbonate, another calcium supplement. In all the patients the treatment is taken through the mouth. The treatment will last for three years.

What are the possible benefits and risks of participating?
Participants enrolled in this study are receiving a treatment that could help them to prevent osteoporosis.

The studied treatments are usually well tolerated. Nevertheless, some people could have constipation, mild nausea, diarrhoea, abdominal disturbances and, very rarely, itchy skin.

Where is the study run from?
The study has been developed in different health centers in an outpatient setting, previously specified, of several Spanish cities (A Coruña, Alicante, Badajoz, Barcelona, Bilbao, Santander, Castellón, Guadalajara, Las Palmas, León, Lugo, Madrid, Murcia Tarragona, Valencia, Zamora and Zaragoza).

When is the study starting and how long is it expected to run for?
The study begun in 2002 and patient inclusion finished in 2008.

Who is funding the study?
The study is funded by Pierre Fabre Ibérica S.A.

Who is the main contact?
José Manasanch
(jose.manasanch@pierre-fabre.com)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PROP-02A

Study information

Scientific Title

Pharmacovigilance observational study of two calcium supplements in the prophylaxis of the osteoporosis in the perimenopause: a longitudinal study

Acronym
PROP

Study objectives
To confirm that ossein-hydroxyapatite complex shows a higher tolerability than calcium carbonate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study did not require ethics approval at the time of initiation as in 2002, in Spain, ethics approval was not mandatory for observational studies related to pharmacovigilance using registered and marketed calcium supplements in an approved indication.

It was approved by the Spanish Medicines Agency, Ministry of Health on the 05/03/2002.

Study design
Observational, multicentre, prospective, open-label, comparative study with a follow-up of three years.

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
No participant information sheet available.

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

Interventions
Patients in the ossein-hydroxyapatite complex (OHC) arm took two tablets of OHC every 12 hours (830 mg OHC per tablet), by oral route, along three years.

Patients in the calcium carbonate (CC) group took one tablet every 12 hours (1,250 CC mg per tablet), by oral route, along three years.

As an observational study, carried out in the real-world practice, there were no randomisation.

Intervention Type
Supplement

Primary outcome measure
Measured using patient interview at follow-up visits every 6 months for 3 years:
1. The number of patients with at least one adverse reaction
2. The severity of the adverse reaction.
3. The relationship of the adverse reaction with the study medication
4. The actions taken in response to the adverse reaction.
5. The outcome of the adverse reaction.
6. The duration of the adverse drug reaction

Secondary outcome measures
1. Bone mineral density was measured by DEXA every 18 months.
2. BMI (kg/m2) was measured every 18 months.
3. The waist hip ratio (%) was measured every 18 months.
4. Lipid metabolism was measured using laboratory analytical data yearly.
5. Bone fractures taking place during the study period were registered at each 6-month follow-up visit.
6. Climacteric (menopausal) symptom changes were measured using the GEM scale every 18 months.
7. Treatment compliance was assessed by means of patient interview at each follow-up (every 6 months).

Overall study start date
03/09/2001

Completion date
12/07/2011

Eligibility

Key inclusion criteria
1. Patients with an indication for the use of CC or OHC according to the investigator criteria.
2. Perimenopausal women between 40 and 50 years old.
3. Patients treated in an outpatient setting.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Initially 1,024 patients were expected to be included in the study.

Key exclusion criteria

1. Patients with severe osteopenia (diagnosed by DEXA, bone mineral density [BMD] ≤ -2 standard deviation [SD] T-score) or osteoporosis (BMD ≤ -2.5 SD T score)
2. Patients who were being treated with a drug that could have compromised bone metabolism such as: glucocorticoids, steroids, thyroid hormones, heparins (in long-term treatment), anticonvulsants, anovulatory drugs, hormone replacement therapy, lithium, chemotherapy, selective estrogen-receptor modulator (SERM), immunosuppressive therapy, and bisphosphonates. A minimal washout period of 6 months was established for any of the previous treatments prior to including the patient in the study.
3. Patients with severe hypercalcaemia or hypercalciuria.
4. Pregnant patients.
5. Concomitant diseases that could have affected bone metabolism: acromegaly, hyperthyroidism, primary hyperparathyroidism, anorexia nervosa, Cushing's syndrome, rheumatoid arthritis, renal diseases, renal lithiasis, diabetes mellitus, and chronic liver disease.
6. Concomitant metabolic bone disease: osteomalacia, Paget's disease.
7. Neoplastic disease developed in the last 5 years, with the exception of skin neoplasias treated with a radical treatment.
8. Known allergy to any compound of the study drugs.
9. Gastrointestinal disorders that could interfere with drug absorption.
10. Women with an expected difficult follow-up due to psychological, cognitive or social circumstances.
11. Patients with foreseen low compliance, difficult follow-up and/or poor collaboration, or with foreseen risk of withdrawal over a minimum period of 3 months due to dementia, alcoholism, terminal illness, etc.

Date of first enrolment
25/07/2002

Date of final enrolment
02/06/2011

Locations

Countries of recruitment
Spain

Study participating centre
Centro Ntra Sra Belén
Teniente Coronel Teijeiro, 3
A Coruña
Spain
15011

Study participating centre
H G U Alicante
Pintor Baeza, 11

Alicante
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03010

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Caramanxel, s/n
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03804

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Pol Adeslas
Carmen, 22
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50005

Study participating centre
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Gran Vía, 27
Zaragoza
Spain
50006

Study participating centre
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50004

Sponsor information

Organisation
Javier Haya Palazuelos

Sponsor details
Sicomoro, 11
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Sponsor type
Other

Funder(s)

Funder type
Industry

Funder Name
Pierre Fabre Ibérica, S.A.

Results and Publications

Publication and dissemination plan
Results about safety and efficacy are intended to be published, along 2019, in a peer-reviewed medicine journal addressed to clinicians of several specialities.

Intention to publish date
21/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from José Manasanch, jose.manasanch@pierre-fabre.com.

The data (raw data and statistical analysis) will become available as soon as the results will be published and could be requested for a minimum of three years after this date if needed for investigational purposes. A formal request will be necessary.

Patients meeting the selection criteria were included in the study after providing informed consent that remain in the investigator files. Any data from the patients was anonymized from inclusion in the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at EMAS Congress :	01/05/2015		No	No
Basic results		22/01/2019		No	No