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Effect on bone turnover and Bone Mineral Density (BMD) of low dose oral silicon as an adjunct to calcium/vitamin D3 in a randomised, placebo-controlled trial

Submission date
05/12/2007

Registration date
07/01/2008

Last Edited
04/07/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

n° 00/1

Study information

Scientific Title
Effect on bone turnover and Bone Mineral Density (BMD) of low dose oral silicon as an adjunct to calcium/vitamin D3 in a randomised, placebo-controlled trial

Study objectives
To investigate the effect of low dose oral silicon as an adjunct to calcium/vitamin D3 on markers of bone turnover and BMD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from St Thomas Hospital Local Research Ethics Committee on the 20th March 2001 (ref: EC01/009).

Study design
Double blind, placebo controlled randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Subjects who meet the inclusion and exclusion criteria were randomly assigned to four groups to take by oral route choline-stabilized Orthosilicic Acid (ch-OSA) or a placebo daily for 12 months. Three different ch-OSA doses (3, 6 and 12 drops) were used corresponding to 3, 6, and 12 mg Si. The placebo group was divided in 3 subgroups (3, 6, and 12 drops) to mimic the three different ch-OSA dosages. The study medication was delivered in sealed 30 ml plastic bottles. The subjects were instructed to mix the ch-OSA or placebo drops with 50 ml (2 floz, 1/4 glass) water or juice and to consume immediately, preferably 30 minutes before a meal or 2 hours after a meal. All subjects received calcium and vitamin D3 (Calcichew/D3 forte, Shire, UK) containing 1000 mg calcium and 20 mg cholecalciferol daily.

A basic clinical examination was performed at each visit. Blood samples and single void urine samples were collected from fasting subjects at baseline and after 12 months supplementation to evaluate the safety parameters. Bone Mineral Density (BMD) was assessed by DEXA using a Hologic QDR 4500 W (Waltham, MA). Scans of the lumbar spine (L1 to L4) and femur (neck, trochanter, intertrochanteric area, Wards triangle and total) were performed at screening and /or at the inclusion visit and then after 12 months treatment at the final visit. Biochemical markers of bone formation (Osteocalcin [OC], Bone-specific Alkaline Phosphatase [BAP], Procollagen type I N-terminal Propeptide [PINP]) and bone resorption (Deoxypyridoline [DPD], C-terminal telopeptide of type I collagen [CTX-I]) were measured at baseline and after 6 and 12 months of treatment.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Silicon, calcium, vitamin D3 supplementation

Primary outcome measure
1. The effect of oral ch-OSA on BMD, measured at baseline and after 12 months
2. The effect of oral ch-OSA on markers of bone turnover, measured at baseline and after 6 and 12 months of treatment

Secondary outcome measures
1. Ch-OSA related adverse events, measured at baseline and after 12 months treatment
2. Biochemical safety parameters of oral use of ch-OSA, measured at baseline and after 12 months treatment

Overall study start date
01/06/2001

Completion date
01/02/2004

Eligibility

Key inclusion criteria
1. Osteopenic, but otherwise healthy
2. Caucasian women with a T-score less than -1.5 at the lumbar spine by Dual Energy X-ray Absorptiometry (DEXA) scan
3. Age range: mean age of 60.7 ± 10.4 years; gender of participants: female

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
184

Key exclusion criteria
Patients were excluded according to the following criteria:
1. Renal failure as defined by serum creatinine greater than 200 µmol/L
2. Abnormal serum ferritin level (normal range: 11 - 250 µg/L)
3. Concomitant medication (treatment with phosphate-binding antacids greater than 6 months /year)
4. Oral glucocorticoid treatment (greater than 8 months in the previous year and greater than 7.5 mg/day prednisone equivalent, or a total dose of more than 2 g prednisone equivalent in the previous 12 months)
5. Local injectable glucocorticoid treatment if greater than 5 injections per year
6. Inhaled glucocorticoid treatment if greater than 6 months in the previous year and more than 2 mg/day prednisone equivalent (glucocorticoids by local topical administration were not excluded)
7. Concomitant or previous treatment for bone diseases:
7.1. Fluoride salts: greater than 10 mg/day, for more than 2 weeks in the previous 12 months
7.2. Biphosphanates: for more than 2 weeks in the previous 12 months
7.3. Oral estrogens
7.4. Estradiol vaginal ring
7.5. Anti-estrogens
7.6. Progesterones
7.7. Anabolic steroids in the previous 3 months or used for more than 1 month in the previous 6 months
7.8. Estradiol implants in the previous 3 years
7.9. Ipriflavone use in the previous 6 months or used for more than 1 month in the previous 12 months
7.10. Calcitonin use in the previous month or used for more than 1 month in the previous 6 months
8. Other drugs for bone disease currently in development
9. Concomitant and previous use of food supplements containing silicon or horsetail herb extract, bamboo extract, colloidal silicic acid, or silanol derivatives in the previous 6 months

Date of first enrolment
01/06/2001

Date of final enrolment
01/02/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Twin Research and Genetic Epidemiology Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Bio Minerals N.V. (Belgium)

Sponsor details
Zenderstraat 12
Destelbergen
Belgium
9070

Sponsor type
Industry

Funder(s)

Funder type
Charity

Funder Name
National Osteoporosis Society (UK)

Alternative Name(s)
NOS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/06/2008		Yes	No