Effect on bone turnover and BMD of low dose oral silicon as an adjunct to calcium/vitamin D3 in a randomized, placebo-controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20097

Source
NTR

Brief title
N/A

Health condition

1. Osteopenia;

2. orthosilicic acid;

3. BMD;

4. bone markers.

Sponsors and support

Primary sponsor: 1. Twin Research and Genetic Epidemiology Unit, St Thomas' Hospital, Kings College, London, United Kingdom;
2. Department of Pharmaceutical Sciences, Faculty of Pharmaceutical, Biomedical and Veterinary Sciences, University of Antwerp, Antwerp, Belgium;
3. MRC Human Nutrition Research, Elsie Widdowson Laboratory, Cambridge, United Kingdom.

Source(s) of monetary or material Support: Grant from the National Osteoporosis Society UK.

Intervention

Outcome measures

Primary outcome

1. The effect of oral choline-stabilized orthosilicic acid (ch-OSA) on markers of bone turnover and bone mineral density (BMD).

Secondary outcome

1. Ch-OSA related adverse events;

2. Biochemical safety parameters of oral use of ch-OSA.

Study description

Background summary

Background:

Mounting evidence supports a physiological role for silicon (Si) as orthosilicic acid (OSA, Si(OH)4) in bone formation. The effect of oral choline-stabilized orthosilicic acid (ch-OSA) on markers of bone turnover and bone mineral density (BMD) was investigated in a double-blind placebo-controlled trial.

Methods:

Over 12–months, 136 women out of 184 randomized (T-score spine < -1.5) completed the study and received, daily, 1000 mg Ca and 20 µg cholecalciferol (Vit D3) and three different ch-OSA doses (3, 6 and 12 mg Si) or placebo. Bone formation markers in serum and urinary resorption markers were measured at baseline, and after 6 and 12 months. Femoral and lumbar BMD were measured at baseline and after 12 months by DEXA.

Results:

Overall, there was a trend for ch-OSA to confer some additional benefit to Ca and Vit D3 treatment, especially for markers of bone formation, but only the marker for type I collagen formation (PINP) was significant at 12 months for the 6 and 12 mg Si dose (vs. placebo) with a trend for a dose-corresponding increase in the bone resorption marker, collagen type I C-terminal telopeptide (CTX-I).
Lumbar spine BMD did not change significantly. Post-hoc subgroup analysis (baseline T-score femur < -1) however was significant for the 6 mg dose at the femoral neck (T-test).

Conclusions:

This study suggests that combined therapy of ch-OSA and Ca/Vit D3 is a safe, well tolerated treatment of potential use in osteoporosis. It has a potentially beneficial effect on bone turnover, especially bone collagen compared to Ca/Vit D3 alone.

Study objective

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

Study design

N/A

Intervention

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 Dual-Energy X-ray Absorptiometry (DEXA) using a Hologic QDR 4500 W (Waltham, MA). Scans of the lumbar spine (L1 to L4) and femur (neck, trochanter, intertrochanteric area, Ward’s 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.

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Eligibility criteria

Inclusion criteria

1. Osteopenic, but otherwise healthy;

2. Caucasian women with a T-score < -1.5 at the lumbar spine by DEXA scan.

Exclusion criteria

1. Patients were excluded according to the following criteria:

a. Renal failure as defined by serum creatinine > 200 µmol/L;

b. Abnormal serum ferritin level (normal range: 11-250 µg/L);

c. Concomitant medication (treatment with phosphate-binding antacids > 6 months / year);

d. Oral glucocorticoid treatment (> 8 months in the previous year and > 7.5 mg/day

prednisone equivalent, or a total dose of more than 2 g prednisone equivalent in the previous 12 months);

e. Local injectable glucocorticoid treatment if > 5 injections per year;

f. Inhaled glucocorticoid treatment if > 6 months in the previous year and more than 2 mg/day prednisone equivalent (glucocorticoids by local topical administration were not excluded);

g. Concomitant or previous treatment for bone diseases (fluoride salts: > 10 mg/day, for more than 2 weeks in the previous 12 months;

h. Biphosphanates: for more than 2 weeks in the previous 12 months;

i. Oral estrogens;

j. Estradiol vaginal ring;

k. Anti-estrogens;

l. Progesterones;

m. Anabolic steroids in the previous 3 months or used for more than 1 month in the previous 6 months;

n. Estradiol implants in the previous 3 years;

o. Ipriflavone use in the previous 6 months or used for more than 1 month in the previous 12 months;

p. Calcitonin use in the previous month or used for more than 1 month in the previous 6 months;

q. Other drugs for bone disease currently in development);

r. 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.

Study design

Design

Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2001
Enrollment:	184
Type:	Actual

Ethics review

Positive opinion

Date:	30-07-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1000
NTR-old	NTR1029
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

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