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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20097

Bron
NTR

Verkorte titel
N/A

Aandoening

1. Osteopenia;

2. orthosilicic acid;

3. BMD;

4. bone markers.

Ondersteuning

Primaire 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.
Overige ondersteuning: Grant from the National Osteoporosis Society UK.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Osteopenic, but otherwise healthy;

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2001
Aantal proefpersonen:	184
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-07-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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