

Does vitamin D improve bone health?

Submission date 24/03/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/06/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 03/03/2017	Condition category Musculoskeletal Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The incidence of bone fractures later in life is higher amongst women who have previously suffered from anorexia (eating disorder). The purpose of this trial is to investigate whether treatment with vitamin D, in either a standard or a high dose, can improve bone health in female patients with anorexia. The study will provide information on vitamin D metabolism in anorexia and on what doses are to be recommended in that disease.

Who can participate?

Female patients with anorexia and female blood donors, who are over 18 years, can participate in this study.

What does the study involve?

The study is a randomized, double-blind prospective, two center trial. The study will compare daily vitamin D3 supplementation with either a standard dose (400 IUs (n= 50) or a higher dose with a target S-25 (OH) vitamin D concentration 75-125 nmol/L (n=50). The patients (100) are followed for two years with blood samples, anthropometric measurements and DEXA. As comparison a group of female blood donors (100) are used.

What are the possible benefits and risks of participating?

Possible benefits: an increased understanding of bone disease in anorexia and of suitable doses of vitamin D in anorexia.

Possible risks: a small risk of side effects from vitamin D and calcium exists (constipation, nausea, abdominal pain, diarrhea and an even smaller risk of kidney stones).

Where is the study run from?

The study is run from Kalmar and Linköping, Sweden.

When is the study starting and how long is it expected to run for?

The study started in February 2013 and is expected to continue until February 2016.

Who is funding the study?

The study is funded by FORSS: Medical Council of Southeast Sweden.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2011-005228-17

Protocol serial number

FORSS-232891

Study information

Scientific Title

Does treatment with vitamin D lower the incidence of osteoporosis in female patients with anorexia?

Study objectives

Treatment with high doses of vitamin D lowers the incidence of osteoporosis in patients with anorexia nervosa.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dnr 2012/145-31 (EPN Linköping, Sweden 2012-05-23)

Primary study design

Interventional

Study design

Randomised controlled study.

Study type(s)

Prevention

Health condition(s) or problem(s) studied

1. Anorexia nervosa (weight fobia, BMI < 17.5, lack of menstration for 3 consecutive months).
2. Osteoporosis

Interventions

100 female patients with anorexia nervosa are randomised to two groups. Bone markers and bone density are followed throughout the study.

1. 1 tablet of: Calcium carbonate 500 mg + Colecalciferol 400 IE p os daily
2. 1 tablet of: Calcium carbonate 500 mg + Colecalciferol 400 IE p os daily + Colecalciferol (oil drops 80 IE/drop) p os.daily. The initial dose of the vitamin D oil drops is 1600 IE. This dose is adjusted from the patients plasma concentration of vitamin D (goal: 90 - 125 nmol/L). The total dose of vitamin D is not to exceed 4000 IE/day.

Each patient is on either of these two treatments for two years and is also monitored for this period of time.

Control group: blood donors

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Bone density: C-teleopeptide of collagen type I (s-CTX) and osteocalcin
25-OH vitamin D3 is measured at baseline, 1, 2, 3, 6, 12, 18 and 24 months. A dual energy X-ray absorptiometry (DXA) is performed at baseline, after 12 and 24 months. Pituitary hormones and after 24 months. Bone markers (C-teleopeptide of collagen type I, osteocaline) are measured at baseline and at 6, 12, 18 and 24 months.

Key secondary outcome(s)

Omega-3 fatty acids, insulin resistance and pituitary hormones. Glucose and insulin are measured at baseline and 18 months.

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. 100 female (age above 18 years) patients that fullfill the criteria of anorexia nervosa, are willing to participate in the study and do not fullfill the exclusion criteria.
2. 100 female blood doners with an age above 18, and willing to participate in the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Treatment with lithium, bisfosfonates, antiepileptics or cortison
2. Allergy towards any substance that are part of the vitamin D or calcium medication of the study or allergy towards soja, peanats
3. Hyperkalcemia, a history of kidney stones or a vitamin D plasma concentration (25-OH-D3) >90 nmol/L or an estimated GFR < 40 ml/min
4. Pregnancy

Date of first enrolment

01/02/2013

Date of final enrolment

01/02/2016

Locations**Countries of recruitment**

Sweden

Study participating centre**Sec of EWndocrinology**

Kalmar

Sweden

SE 392 47 Kalmar

Sponsor information**Organisation**

Kalmar County Hospital (Sweden)

ROR

<https://ror.org/04g3stk86>

Funder(s)

Funder type

Research council

Funder Name

FORSS: Medical Research Council of Southeast Sweden (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration