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Does vitamin D improve bone health?

Submission date
24/03/2013

Recruitment status
No longer recruiting

Registration date
14/06/2013

Overall study status
Completed

Last Edited
03/03/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 bloodsamples , 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

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Additional identifiers

EudraCT/CTIS number
2011-005228-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Randomised controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

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 measure
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.

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

Overall study start date
01/02/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
100 patients with anorexia + 100 controll subjects (blood doners).

Key exclusion criteria
1. Treatment with litium, 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)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04g3stk86

Funder(s)

Funder type
Research council

Funder Name
FORSS: Medical Research Council of Southeast Sweden (Sweden)

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