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Vitamin D supplementation in the obese

Submission date	Recruitment status	[ ] Prospectively registered
02/04/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/04/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2014	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Severely obese people tend to score poorly on tests of physical function and are at increased risk of dying prematurely. Roughly two thirds of severely obese people have low vitamin D levels. We wish to determine if vitamin D supplementation can improve physical function in people with both severe obesity and a low vitamin D level.

Who can participate?
You can participate if you are aged between 18 and 65 years and if you have severe obesity (a body mass index greater than 40 kg/m2).

What does the study involve?
We will measure how long it takes you to walk 500 metres, at a moderately intense pace. If you have a low vitamin D level and you are willing to take a vitamin D supplement we will supply you with tablets containing vitamin D and calcium which you will be expected to take twice daily for 12 weeks. If your vitamin D level is not low or if you do not want to take a vitamin D supplement we would still like to measure how long it takes you to walk 500 metres after 12 weeks of no vitamin D supplementation. This will allow us compare the effects of vitamin D supplementation to the effects of no supplementation. Other ways that we will measure physical function will include timing how long it takes you to rise from a chair five times without using your hands and how long it you to walk 3 metres starting from and finishing in a seated position.

What are the possible benefits and risks of participating?
Less than 1% of people who take a vitamin D supplement will develop high calcium levels in their blood or urine. Less than 0.1% of people who take a vitamin D supplement will experience gastrointestinal symptoms (vomiting, diarrhoea, constipation) or a skin rash. Vitamin D supplements can decrease your risk of falling or of suffering a broken bone. Some studies show that vitamin D supplements may decrease the risk of diabetes and certain cancers.

Where is the study run from?
We will conduct this trial in St Columcilles Hospital (Ireland).

When is the study starting and how long is it expected to run for?
The study ran from August 2011 to April 2013.

Who is funding the study?
St Columcilles Hospital (Ireland).

Who is the main contact?
Dr Tomás Ahern
cuthbertmuldoon@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Donal O'Shea

Contact details
Department of Endocrinology
St Columcille's Hospital
Loughlinstown
Dublin
Ireland
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VitD2011-1

Study information

Scientific Title
Vitamin D supplementation in the obese: a pilot study

Study objectives
Vitamin D supplementation improves physical function in the severely obese

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Vincent's Healthcare Group Ethics and Medical Research Committee, 11/07/2011, ref: Ahern July 11

Study design

Single-centre prospective parallel-arm interventional study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Severe obesity, vitamin D deficiency

Interventions
Participants are allocated to the vitamin D supplementation (Caltrate®) arm if their serum 25-hydroxyvitamin D concentration is less than 50 nmol/L AND if they are willing to commence vitamin D supplementation. Participants are allocated to the no-treatment parallel arm if their serum 25-hydroxyvitamin D concentration is greater than 50 nmol/L OR if they are unwilling to commence vitamin D supplementation.

All participants allocated to the treatment arm will receive a 12-week supply of Caltrate® (containing 600 mg of calcium and 400 units of vitamin D per tablet) and be expected to take one tablet twice daily. Participants in the parallel, no-treatment arm will be expected to not take a calcium and vitamin D supplement.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Caltrate® (Vitamin D)

Primary outcome measure
The change in the time taken to walk 500 m at a moderately intense pace measured at 6 weeks before treatment, 0 weeks before treatment and 12 weeks after treatment

Secondary outcome measures
Change in the:
1. Time taken to complete an Up And Go Test (UAG, timed 3 metre walk starting from and finishing in a seated position)
2. Time taken to rise from a chair five times

3. Ability to complete tests of standing balance
4. Grip strength
5. Scores on quality of life questionnaires (SF-36, EQ-5D, ESS)
6. Number of peripheral blood mononuclear cell subsets
7. Serum hormone, bone turnover marker and cytokine concentrations
8. Blood pressure
9. Weight
10. Physical activity level

Measured at 6 weeks before treatment, 0 weeks before treatment and 12 weeks after treatment.

Overall study start date
01/08/2011

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Body mass index is greater than 40 kg/m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Known hypersensitivity to the active substances or any of the excipients of Caltrate®
2. Known hypersensitivity to soya or to peanut
3. Stage 4 or Stage 5 chronic kidney disease (eGFR < 30 ml/min/1.78m2)
4. Nephrolithiasis
5. Hypercalcaemia (serum calcium concentration > 2.6 mmol/L)
6. Pregnancy
7. Lactation

8. Psychotic mental illness
9. Inability to understand the participant information or to give informed consent
10. Any clinically significant chronic disease that might, in the opinion of the investigator, interfere with the evaluations or preclude completion of the trial (e.g., severe chronic lung disease, terminal illness)
11. Participation in a clinical trial during the 12 weeks prior to study entry (i.e., prior to screening visit)

Date of first enrolment
01/08/2011

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Endocrinology
Dublin
Ireland
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Sponsor information

Organisation
St Vincent's University Hospital (Ireland)

Sponsor details
Obesity Research Group
Education and Research Centre
Elm Park
Dublin
Ireland
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Sponsor type
Hospital/treatment centre

Website
http://www.stvincents.ie/

ROR

https://ror.org/029tkqm80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Columcille's Hospital (Ireland)

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