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Vitamin D supplementation and muscle strength in sarcopenic and obese sarcopenic elderly Lebanese people

Submission date
02/06/2017

Recruitment status
No longer recruiting

Registration date
06/06/2017

Overall study status
Completed

Last Edited
14/07/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Sarcopenia is a condition associated with old age, which involves loss of muscle mass and strength. This can lead to problems with balance and movement, increasing the risk of falling and fractures in the elderly. Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D plays an important role in muscle and bone health. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. Vitamin D deficiency or insufficiency is a common health problem in older adults. It has been found that obese older adults have low vitamin D levels and low muscle strength and mass (sarcopenic obesity). The aim of this study is to look at the effects of vitamin D supplementation on sarcopenic individuals and individuals with sarcopenic obesity.

Who can participate?
Adults aged 70 and over who are deficient in vitamin D.

What does the study involve?
Participants are randomly allocated to one of four groups. Those in the first and third group are obese and those in the second and fourth group are of normal weight. In each pair of groups, one group receives a weekly supplement of vitamin D for six months, and the other receives a weekly supplement containing a placebo (dummy pill) for six months. At the start of the study and then six months later, participants have a blood test to assess their vitamin D levels, as well as being weighed and taking parts in assessments of muscle strength and function.

What are the possible benefits and risks of participating?
Participants who receive the vitamin D may benefit from improved muscle strength and function. There is a small risk of pain or bruising when blood samples are collected.

Where is the study run from?
Saint Charles Hospital (Lebanon)

When is study starting and how long is it expected to run for?
April 2015 to September 2015

Who is funding the study?
Saint Charles Hospital (Lebanon)

Who is the main contact?
Ms Cynthia El Hajj
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title
Effect of vitamin D supplementation on muscle mass and strength in sarcopenic and obese sarcopenic older Lebanese people

Study objectives
The aim of this study is to evaluate the effects of weekly supplement of 10,000 IU cholecalciferol (Euro-Pharm International, Canada) over 6 months on muscle strength and sarcopenia.

Null hypothesis:
Vitamin D supplementation will not have effect on muscle strength and sarcopenia of the participants.

Alternative hypothesis:
Vitamin D supplementation will increase muscle mass and decrease sarcopenia of the participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee Ethical Approval Form (CEAF) of Saint Charles Hospital, 11/05/2015, ref: 11/5

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Vitamin D deficiency

Interventions
Participants are randomised to one of four groups. Those in group one and three have a BMI over 30 and those in groups two and four have a BMI within the normal range.

Group 1: Participants receive a weekly supplement of 10,000 IU cholecalciferol (vitamin D) for 6 months
Group 2: Participants receive a weekly supplement of 10,000 IU cholecalciferol (vitamin D) for 6 months
Group 3: Participants receive a weekly supplement of a placebo tablet (containing microcrystalline cellulose: 66.3%, starch: 33.2%, magnesium stearate: 0.5%, per serving) for 6 months
Group 4: Participants receive a weekly supplement of a placebo tablet (containing microcrystalline cellulose: 66.3%, starch: 33.2%, magnesium stearate: 0.5%, per serving) for 6 months

Follow up takes place after six months and involves phone calls every three months and assessment at baseline and after 6 months of supplementation.

Intervention Type
Supplement

Primary outcome measure
All primary outcomes are assessed at baseline and after 6 months of intervention.
1. Vitamin D (25(OH)D) is measured by radioimmunoassay (DiaSorin, Stillwater, MN)
2. Handgrip strength is measured in the dominant hand with a Martin vigorimeter (Martin; Elmed, Addison, IL, USA), and the force was expressed in kilograms (kg)
3. Skeletal muscle mass is anticipated from bioimpedance analysis measurements (Tanita BC-418 Segmental Body Composition Analyzer, Illinois, USA) and expressed as appendicular skeletal muscle mass (ASMM, kg)
4. Total lean body mass is measured using Tanita BC-418 Segmental Body Composition Analyzer, Illinois, USA
5. Fat mass is measured using Tanita BC-418 Segmental Body Composition Analyzer, Illinois, USA
6. Parathyroid hormone is measured using a two-site immunoradiometric assay with an NH2-terminal monoclonal antibody as capture (Fitzgerald Industries International Inc., USA)

Secondary outcome measures
All secondary outcomes are assessed at baseline and after 6 months of intervention.
1. Weight (kg) is assessed using the body composition analyzer (Tanita BC-418 Segmental Body Composition Analyzer, Illinois,USA)
2. Body mass index (BMI) is calculated using the standard formula (body weight in kilograms divided by the square of the body height in meters [kg/m^2])
3. Serum creatinine is measured using the Jaffe rate method, the kinetic alkaline picrate (Interpretation and Techniques, Lea and Febiger, Philadelphia)

Overall study start date
06/04/2015

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Deficient in vitamin D
2. Age 70 years and over
3. No medical history of type 2 diabetes, congestive heart failure, renal failure or acute heart insufficiency

Participant type(s)
Healthy volunteer

Age group
Senior

Sex

Both

Target number of participants
116

Key exclusion criteria
1. Not deficient in vitamin D
2. Under 70 years of age
3. Having a medical history of type 2 diabetes, congestive heart failure, renal failure or acute heart insufficiency

Date of first enrolment
02/07/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
France

Lebanon

Study participating centre
Saint Charles Hospital
Fayadié-Baabda-Liban
Beirut
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50

Sponsor information

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Saint Charles Hospital

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
15/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Cynthia El Hajj (cynthiaeliashajj102@gmail.com)

IPD sharing plan summary
Available on request