ISRCTN16665940 https://doi.org/10.1186/ISRCTN16665940

Vitamin D supplementation and sarcopenia

Submission date	Recruitment status	[_] Prospectively registered
12/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/12/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
The term sarcopenia means the loss of muscle mass and muscle function with age, especially among elderly people. Previous studies have shown that improving vitamin D status among the elderly may lead to an improvement in muscle mass and muscle strength. The aim of this study is to examine the effect of vitamin D supplementation on muscle mass and strength in sarcopenic older Lebanese people.

Who can participate?
Adults aged 71-77 who are deficient in vitamin D.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive vitamin D supplments. Those in the second group receive a dummy supplement. Participants take the supplement for six months. Participants are followed up to assess strength and functional assessment and biochemical analysis after six months to see if they have improved.

What are the possible benefits and risks of participating?
Participants may benefit from vitamin D supplementation as it may improve muscle strength and sarcopenia. No risks are involved in the participants taking part in the study.

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

When is the study starting and how long is it expected to run for?
August 2014 to December 2015

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

Who is the main contact?
Miss El Hajj Cynthia (Scientific)
cynthiaeliashajj102@gmail.com

Contact information

Type(s)
Scientific

Contact name
Miss El Hajj Cynthia

Contact details
Universite d'Auvergne
49 Boulevard François Mitterrand
Clermont-Ferrand
France
63000
+33 4 73 60 82 76
cynthiaeliashajj102@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SSCC012

Study information

Scientific Title
Vitamin D supplementation and muscle strength in sarcopenic elderly Lebanese people: A randomised controlled trial

Study objectives
Vitamin D supplementation has beneficial effects on muscle strength and muscle mass in elderly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Institutional Review Board Saint Charles Hospital, 11/02/2015, ref: SSCC012

Study design
Randomided controlled double blind study

Primary study design
Interventional

Secondary study design
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
Sarcopenia and Vitamin D Deficiency

Interventions
In this randomized, controlled, double blind study, participants are randomized (using the simple randomization method) to receive either a supplement of 10,000 IU of cholecalciferol (Euro-Pharm International, Canada) or a placebo tablet (containing microcrystalline cellulose: 66.3%, starch: 33.2%, magnesium stearate: 0.5%, per serving) to be taken three times per week for a period of six months.

The participants are seen after six months of supplementation with vitamin D or placebo, and followed up by phone calls at three months.

Intervention Type
Supplement

Primary outcome measure
1. Handgrip strength is measured using the Martin vigorimeter (Martin; Elmed, Addison, IL, USA), at baseline and 6 months.
2. Appendicular skeletal muscle mass is measured using bioimpedance analysis measurements (Tanita BC-418 Segmental Body Composition Analyzer, Illinois, USA) at baseline and 6 months.
3. 25 (OH)D levels are measured using radioimmunoassay (DiaSorin, Stillwater, MN) at baseline and 6 months

Secondary outcome measures
1. Weight is measured using the body composition analyzer (Tanita BC-418 Segmental Body Composition Analyzer, Illinois, USA) at baseline and 6 months
2. BMI is calculated using the standard formula (body weight in kilograms divided by square of body height in meters). at baseline and 6 months
3. Waist circumference is measured at the iliac crest at baseline and 6 months
4. Fat Mass is measured using the body composition analyzer (Tanita BC-418 Segmental Body Composition Analyzer, Illinois, USA) at baseline and 6 months
5. PTH is measured using a two-site immunoradiometric assay with an NH2-terminal monoclonal antibody as capture (Fitzgerald Industries International Inc., USA), at baseline and 6 months
6. Serum creatinine is measured using the Jaffe kineticalkaline picrate reaction (Interpretation and Techniques, Lea and Febiger, Philadelphia), at baseline and 6 months

Overall study start date
02/08/2014

Completion date

04/12/2015

Eligibility

Key inclusion criteria
1. Sarcopenic
2. Deficient in vitamin D
3. No medical history of type-2 diabetes
4. Age range of participants: 71-77

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
115

Key exclusion criteria
1. Sarcopenic subjects
2. Incidence of balance problems due to neurological disorders
3. Renal failure
4. Congestive heart failure and acute heart insufficiency as well as uncontrolled arterial hypertension or hypotension
5. Use of sedative (that could affect balance)
6. Use of vitamin D supplementation
7. Primary hyperparathyroidism

Date of first enrolment
02/07/2015

Date of final enrolment
19/09/2015

Locations

Countries of recruitment
Lebanon

Study participating centre
Hopital Saint Charles
Fiyadiyeh- Baabda

Beirut
Lebanon
50

Sponsor information

Organisation
Universite d'Auvergne

Sponsor details
49 Boulevard François Mitterrand
Clermont-Ferrand
France
63000

Sponsor type
Other

Website
https://www6.clermont.inra.fr/unh/Equipes-de-Recherche/ASMS/Composition-de-l-equipe/Dr-Stephane-WALRAND

ROR
https://ror.org/01a8ajp46

Funder(s)

Funder type
Not defined

Funder Name
Saint Charles Hospital

Results and Publications

Publication and dissemination plan
Planned publication. Study protocol, statistical analysis plan, and others are available.

Intention to publish date
02/04/2018

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
Email address: cynthiaeliashajj102@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/12/2018		Yes	No