

# Vitamin D supplementation and sarcopenia

<b>Submission date</b> 12/02/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/12/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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 supplements. 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****Protocol serial number**

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**

Randomised controlled double blind study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**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(s)**

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

### **Key secondary outcome(s)**

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 NH<sub>2</sub>-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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Senior

**Sex**

All

**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

Fiyadiyah- Baabda

Beirut

Lebanon

50

**Sponsor information**

**Organisation**

Universite d'Auvergne

**ROR**

<https://ror.org/01a8ajp46>

**Funder(s)**

**Funder type**

Not defined

**Funder Name**

Saint Charles Hospital

## Results and Publications

**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](mailto:cynthiaeliashajj102@gmail.com)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	19/12/2018		Yes	No