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Effects of high dose vitamin D supplementation on muscle mass and muscle strength in frail elderly people

Submission date 11/04/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 11/04/2007	**Overall study status** Completed	
Last Edited 07/04/2011	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr C Oudshoorn

Contact details
Erasmus Medical Centre
Room D442
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 463 5037
c.oudshoorn@erasmusmc.nl

Additional identifiers

Protocol serial number
2007-160

Study information

Scientific Title

Study objectives
Vitamin D improves muscle-mass and -strength which improves overall quality of life in patients with low serum vitamin D levels.

Please note that as of 13/07/10 this record was updated to included changes made to the protocol during the planning phase of the trial (i.e. between the time of registration and the beginning of the recruitment phase). All updates can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 13/07/10:
The Medical Ethics Review Committee (Medisch Ethische Toetsings Commissie), Erasmus Medical Centre approved on the 24th of July 2007 (ref: MEC-2007-160)

Primary study design
Interventional

Study design
Randomised placebo controlled parallel group double blind trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Hypovitaminosis D on muscle mass and strength

Interventions
Current information as of 13/07/10:
Patients were randomised to receive either
1. 1800IU cholecalciferol (vitamin D3) daily
2. Placebo daily
Medications were used for a period of six months. The end date for inclusion into this trial was December 2009.

Initial information at time of registration
Individuals are randomised to recieve either:
1. 1200 IU vitamin D/day and 1000 mg calcium/day
2. Placebo medications and 1000 mg calcium/day

Medications will be used for a period of six months.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
High dose vitamin D

Primary outcome(s)
Differences in muscle strength (handgrip strength and quadriceps strength) between treatment and control group.

Key secondary outcome(s)
1. Changes in mobility:
1.1. Timed up and go test
1.2. Walking distance
2. Quality of life (using the health assessment questionnaire)
3. Falls

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Frail elderly people, aged greater than 65 years
2. Living in homes for the elderly
3. Serum vitamin D level less than 50 nmol/l
Added 07/04/2011:
4: Stable health (including no history of recurrent falling or recent fracture).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Not able to perform muscle strength measurements
2. History of kidney stones, renal insufficiency (less than 40%)
3. Primary hyperparathyroidism
4. Dementia (Mini Mental State Examination [MMSE] less than 20/30 points
5. Life expectancy less than six months
6. Neurodegenerative disorders (Parkinsons, Amyotrophic Lateral Sclerosis [ALS])
7. Use of the following medications:
7.1. Vitamin D
7.2. Bisphosphonates
7.3. Steroids

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration