The effect of Calcifediol (Hy.D 25 SD/S) and Vitamin D3 on muscle strength in a frail elderly population: A randomized, double-blind, placebo-controlled trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41964

Source
ToetsingOnline

Brief title
D-Fit

Condition

- Other condition

Synonym
impaired physical performance, vitamin D deficiency

Health condition

verminderd fysiek functioneren, vitamine D deficientie

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: TI Food and Nutrition

Intervention

Keyword: calcifediol, frail elderly, muscle strength, vitamin D3

Outcome measures

Primary outcome

The change in muscle strength within 24 weeks, the primary outcome measure is knee extension strength test.

Secondary outcome

Secondary outcomes are to assess the change in serum 25(OH)D level, frequency of falling, muscle fibre type and size, muscle mass and body composition, handgrip strength, SPPB, TUG, postural body sway, blood pressure, cognitive functioning and neuromuscular functioning.

Study description

Background summary

In an ageing population, the need for interventions to help older people remain healthy, active and independent for as long as possible, increases. Although several studies suggest a beneficial effect of vitamin D3 in maintaining or improving physical functioning, particularly in vulnerable populations, results are contradicting. Randomized, placebo-controlled trials are needed to further establish the effect of vitamin D in the frail elderly population. Besides supplementation with vitamin D3, one treatment-arm will be supplemented with Calcifediol. Calcifediol is considered to be 2 to 3 times more potent in increasing 25(OH)D concentration up to an optimal level compared to vitamin D3. Therefore, supplementation with the active metabolite may have benefits superior to vitamin D3 on improving muscle strength and performance. The

primary aim of this study is to determine the effect of daily supplementation with two different forms of vitamin D on muscle strength in frail elderly people over a period of 24 weeks.

Study objective

The primary aim of this study is to determine the effect of daily supplementation with two different forms of vitamin D on muscle strength in frail elderly people over a period of 24 weeks. Secondary objectives are to assess the change in serum 25(OH)D level, frequency of falling, muscle fibre type and size, muscle mass and body composition, handgrip strength, Short Physical Performance Battery (SPPB) and TUG test, postural body sway, blood pressure, cognitive functioning and neuromuscular functioning.

Study design

The study will be a randomised, double-blind, placebo-controlled, intervention trial, with 3 treatment arms.

Intervention

Subjects will be randomly allocated to one of the three intervention groups, stratified by gender and BMI (18.5-29.9, 30-35 kg/m2). The three groups will receive, in a double blinded way, supplementations of 10 µg/day Calcifediol (Hy.D 25 SD/S), 20 µg/day vitamin D3 or placebo for an intervention period of 24 weeks.

Study burden and risks

The risks involved in participating in this study are minimal. The doses used in this study have shown to be safe in previous trials. Muscle biopsies will be performed by an experienced physician and will heal completely. There is a small risk of infection and the muscle biopsy can lead to minor hematoma. The risk of the blood collection is merely that of a small local hematoma, feeling light-headed, fainting or an infection. The physical performance tests and strength measurements might result in feelings of muscle soreness. EMG measurements are completely safe. Skin preparation along with placement of the electrodes might result in a skin rash, but generally subsides in a few days. Electrical stimulation can result in the perception of discomfort during the stimulus. To minimize the discomfort, stimuli will be very short in duration (only 100 microseconds in length). For elderly, the social aspect can be an important reason to participate and therefore, study visits will be carried out in small groups. In addition, the subjects will receive a final report of their own results of the performed tests (if it so wishes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 25(OH)D levels 20-50 nmol/L.
- age 65 or older.
- male or female gender.
- physically pre-frail or frail
- body mass index between 18.5 and 35 kg/m2.
- willingness and ability to comply with the protocol, including performance of the knee extension strenght test.

Exclusion criteria

- Medical illness: malabsorption syndrome (known intestinal malabsorption, celiac diseases,

inflammatory bowel disease), diseases that may enhance serum calcium concentration (sarcoidosis, lymphoma, kidney stone in last 10 years, primary hyperparathyroidism), abnormal indices of calcium metabolism, uncontrolled hypocalcaemia, diagnosed renal insufficiency, diagnosed cancer (currently diagnosed or undergoing treatment)
- Hypercalcemia: serum calcium adjusted for albumin of > 2.6 nmol/L.
- Medication: interfering with vitamin D metabolism and vitamin D supplementation; bisphosphonate, PTH treatment, tuberculostatica, anti-epileptica, bile acid sequestrate (Colestyramine, Colestipol) and lipase inhibitors (Orlistat).
- Subject not able (when medically necessary/ advised) or not willing to stop the use of vitamin D containing supplements during the study.
- (Expected) increase in exposure to sunlight (e.g. travelling to a sunny resort) during intervention period.
- Patient heavily consumes alcohol containing products defined as greater than > 21 drinks of alcoholic beverages per week.
- Planned surgery which can affect study measures (taking into account duration of hospitalisation and recovery).
- Participation in another clinical trial.
- Subjects taking anticoagulation medication (with an exception of platelet inhibitors like aspirin) will be included in the study, but excluded from the muscle biopsy procedure.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2015
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	03-06-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	29-09-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	25-06-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48127.081.14