Prevention of depression and poor physical function in older persons with vitamin D supplementation

Published: 09-01-2013
Last updated: 26-04-2024

Primary objectives: 1. Does vitamin D supplementation improve depressive symptoms in older persons? 2. Does vitamin D supplementation improve physical performance and functional limitations in older persons?Secondary objectives: 3. Does vitamin D...

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

Summary

ID

NL-OMON39818

Source
ToetsingOnline

Brief title
D-Vitaal

Condition

- Other condition
- Vitamin related disorders
- Neuromuscular disorders

Synonym
depressive symptoms, poor physical function

Health condition

Depressieve symptomen, matige fysieke functie

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: depression, older persons, poor physical function, vitamin D supplementation

Outcome measures

Primary outcome

Change in the CES-D score, change in physical performance score after 12

months, change in the number of functional limitations as well as change of

degree of functional limitations.

Secondary outcome

Change in anxiety, cognition, quality of life, incidence of full-blown

depression, timed up-and-go-test, costs.

Study description

Background summary

Depressive symptoms are common in older persons, often associated with poor physical function and vitamin D deficiency (serum 25-hydroxyvitamin D < 50 nmol/l). Simple and cheap interventions to prevent depression are lacking. Vitamin D deficiency occurs in 50% of persons >65 yr and has been associated with an increase in depressive symptoms in many studies, as well as with functional limitations and declining physical performance. A prior randomized placebo-controlled trial on the effect of vitamin D supplementation in overweight persons showed a decrease in depressive symptoms. Vitamin D supplementation also had a positive influence on mobility tests in several clinical trials. A mechanistic explanation is available: the vitamin D receptor is present in muscle cells as well as in brain tissue, especially in the hypothalamus. The hypothesis is that vitamin D decreases depressive symptoms and improves physical performance and functional limitations in older persons.

Secondary hypotheses are that vitamin D decreases anxiety, improves cognitive functioning and quality of life, and prevents the development of full-blown depression in older persons.

Study objective

Primary objectives:
1. Does vitamin D supplementation improve depressive symptoms in older persons?
2. Does vitamin D supplementation improve physical performance and functional limitations in older persons?
Secondary objectives:
3. Does vitamin D supplementation decrease anxiety and improve cognitive function and quality of life in older persons?
4. Can vitamin D supplementation prevent the development of full-blown depression in older persons?
5. Is vitamin D supplementation a cost-effective strategy in the prevention of increasing depressive symptoms and functional limitations and declining physical performance?

Study design

A randomized double-blind placebo-controlled intervention study on the effect of vitamin D 1200 IU per day versus placebo on depressive symptoms, physical performance and functional limitations. The duration of intervention and follow-up is one year.

Intervention

The patients are randomized into two groups: vitamin D 1200 IU (three tablets of 400 IU per day) or placebo (three tablets per day) for one year.

Study burden and risks

Potential participants are screened with postal questionnaires and a screening visit to their general practice, a location near their home, or at their home (short questionnaire and blood sample). After screening, they have to come 3 times to the general practice or location near their home (or receive home visits) at baseline, after 6 and 12 months. They have to complete questionnaires, perform physical performance tests, and a blood sample is drawn twice at baseline and 6 months. Assessments at 3 weeks, 3 months and 9 months are by telephone. The risk of the vitamin D treatment is negligible.

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

- age 60-80 years
- mild depressive symptoms
- at least one functional limitation
- serum 25(OH)D levels between 15 and 50 nmol/l (winter) or 15 and 70 nmol/l (summer)
- ability to comply with the study

Exclusion criteria

- full-blown depressive disorder
- use of antidepressants
- vitamin D (more than 400 IU/day) or calcium (more than 1000 mg/day) supplementation

- major life-threatening illness
- living in an aged-people's home or nursing home

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2013
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Devaron
Generic name:	vitamin D3
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	09-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	23-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2012-005332-29-NL
CCMO	NL41567.029.12
Other	NTR3845 (Nederlands Trialregister)

Study results

Results posted: 26-03-2020

First publication
26-03-2020