Health benefits of a vitamin D supplementation program in alcoholism.

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The aims of this study are to observe the effectiveness of oral vitamin D supplementation on vitamin D status and muscle performance in vitamin D-deficient alcoholics during two different vitamin D treatment strategies (VIDIO and CAU).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vitamin related disorders
Study type	Interventional

Summary

ID

NL-OMON39028

Source
ToetsingOnline

Brief title
Vitamin D trial: VIDIO.

Condition

- Vitamin related disorders
- Muscle disorders

Synonym
myopathy., Vitamin D hypovitaminose

Research involving
Human

Sponsors and support

Primary sponsor: Korsakovcentrum Slingedael
Source(s) of monetary or material Support: Particuliere instelling: Bestuur Heilige Geesthuis.

Intervention

Keyword: Alcoholism, cholecalciferol., muscle weakness, vitamin D deficiency

Outcome measures

Primary outcome

Primary outcomes are serum 25(OH)D concentrations.

Secondary outcome

Secondary outcomes include the participants* quadriceps maximal voluntary contractions, gait and balance abilities, and a health-related quality of life evaluation.

Study description

Background summary

Previous studies suggested that muscle weakness in alcoholics was not primarily related to the patient's nutritional status or vitamin B deficiencies. Since vitamin D hypovitaminosis is a well recognised cause of myopathy, the question remains whether muscle weakness in alcoholism may be caused by vitamin D deficiency.

Study objective

The aims of this study are to observe the effectiveness of oral vitamin D supplementation on vitamin D status and muscle performance in vitamin D-deficient alcoholics during two different vitamin D treatment strategies (VIDIO and CAU).

Study design

This study is an open, two-arm randomised controlled trial.

Intervention

This study is a randomised two-arm trial of vitamin D supplementation with Vitamin D Intensive Outreach (VIDIO) including cholecalciferol loading dose, if

applicable, and subsequent (bimonthly) high-dose cholecalciferol through an outreach approach of the Street Doctor Service in Rotterdam, versus Care As Usual (CAU) comprising daily prescription of cholecalciferol 800 IU, available in combination with calcium carbonate. The VIDIO intervention is based upon general principles to enhance medication compliance for successful treatment, disease prevention, and health promotion, by means of a simple medication regime in one-on-one patient contacts.

Study burden and risks

A total number of three blood samples are collected (total volume = 44•5 mL) over one year. The questionnaires usually take around one and a half hour to complete. Total three test sessions of muscle strength and balance testing are of 20 minutes each. Although the dynamometer is padded, tenderness may occur over the dynamometer placement sites especially after repeated trials. Except in those with conditions causing hypersensitivity (primary hyperparathyroidism, sarcoidosis, tuberculosis, or lymphoma) there is no evidence of adverse effects with serum 25(OH)D concentrations <140 nmol/L, which require a total vitamin D supply of 250 µg (10,000 IU) per day to attain.

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

Inclusion criteria are having a history of alcohol abuse and currently living in Rotterdam and vicinity, and serum 25-hydroxyvitamin D concentration below 50 nmol/L at baseline.

Exclusion criteria

Exclusion criteria are a high risk or serious suspicion of Wernicke*s encephalopathy, knee surgery, first year after hip surgery, pregnancy/lactating or trying to conceive, already having vitamin D prescriptions for treatment of osteoporosis or hypo-vitaminosis D myopathy, inability to give informed consent because of mental incapacity, insufficient command of the Dutch language, and contraindications of Calci Chew D3 or cholecalciferol: hypercalcaemia, renal failure (glomerular filtration rate <30 mL/min per 1.73m2), history of tuberculosis, sarcoidosis, lymphomas, hyperparathyroidism, nephrolithiasis/calciuria, and soya or peanut allergy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	17-07-2014
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Calci-Chew D3 500 mg / 800 I.U.
Generic name:	Calcium carbonate 500 mg / Cholecalciferol 800 I.U.
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cholecolciferol (vitamin D) 50,000 I.U. / ml
Generic name:	Cholecolciferol (vitamin D) 50,000 I.U. / ml

Ethics review

Approved WMO Date:	23-05-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2012-002207-17-NL
CCMO	NL40553.078.12