Health Benefits of a Vitamin D Supplementation Program in Alcoholism In Dutch: Vitamine toediening ter verbetering van de gezondheid bij vitamine D gebrek door alcoholgebruik

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23964

Source
NTR

Brief title
VIDIO

Health condition

Engels: Vitamin D deficiency; myopathy.
Nederlands: Vitamine D deficiëntie; myopathie.

Sponsors and support

Primary sponsor: Sponsor: Lelie Zorggroep, location Slingedael Korsakoff Centre. Slinge 901, 3086 EZ Rotterdam, Netherlands.
Source(s) of monetary or material Support: Lelie Zorggroep, location Slingedael Korsakoff Centre. Slinge 901, 3086 EZ Rotterdam, Netherlands.

Intervention

Outcome measures

Primary outcome

Primary outcome measures are serum 25(OH)vitamin D concentrations.

Secondary outcome

Secondary outcome measures are maximal voluntary muscle strength of the participants' dominant quadriceps muscle, the participants' gait and balance abilities, and a health-related quality of life evaluation.

Study description

Background summary

Background: Decreased bioavailability of vitamins may be due to inadequate dietary sources, lower intestinal absorption and/or liver dysfunction. Muscular weakness and wasting is frequently
found in chronic alcoholism and might be related to severe vitamin D hypovitaminosis.

Objective: To evaluate the effect of vitamin D supplementation in alcoholic myopathy through intensive outreach in 12 months follow-up.

Design, Setting and Participants: Participants are community-dwelling adults with a history of alcohol use and who are at risk of multiple vitamin deficiencies. Participants with vitamin D deficiencies of <50 nmol/L serum 25-hydroxyvitamin D (25(OH)D) are randomly allocated to one of
two different strategies of vitamin D supplementation. The Vitamin D Intensive Outreach (VIDIO)
program includes a cholecalciferol loading dose, if applicable, and subsequent bimonthly high-dose
cholecalciferol through an outreach approach of the Street Doctor Service in Rotterdam, the Netherlands. Care As Usual (CAU) includes daily prescriptions of cholecalciferol 800 IU, available in
combination with calcium carbonate, and depending on medication compliance of the participants.

Intervention: 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.
Outcome measures: Primary outcomes are serum 25(OH)D concentrations. Secondary outcomes

include the participants' quadriceps maximal voluntary contractions, gait and balance abilities, results
of cognitive screening, and a health-related quality of life evaluation. Prevalences of vitamin D and B1
deficiencies will be described.

Discussion: Mediating variables of vitamin D status are identified by assessing baseline characteristics, liver function and other laboratory findings, help-seeking behaviour, social support,
and service engagement. Comparison between the two strategies of vitamin D therapy and serum
25(OH)D levels provides insight in the effectiveness of the intervention. Progress in muscle strength
in the VIDIO intervention reflects an effect of vitamin D. Possible associations between results of
cognitive screening and vitamin D or B1 deficiencies are discussed.

Study objective

VIDIO: Vitamin D Intensive Outreach includes a cholecalciferol loading dose, if applicable, and subsequent bimonthly high-dose cholecalciferol through an outreach approach of the Street Doctor Service in Rotterdam. CAU: Care As Usual includes daily prescriptions 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. We hypothesise that vitamin D supplementation may be more effective on vitamin D levels and muscle performance when given through VIDIO, rather than CAU depending upon medication prescriptions and medication compliance of the participants.

Study design

Baseline, 6 months, 12 months.

Intervention

After receiving the baseline laboratory results, an independent Doctor's Assistant allocates participants to one of the two vitamin D supplementation strategies (VIDIO and CAU). Participants with vitamin D deficiencies of <50 nmol/L serum 25-hydroxyvitamin D (25(OH)D) are randomly allocated to one of two different strategies (VIDIO and CAU) of vitamin D supplementation. VIDIO: Vitamin D Intensive Outreach includes a cholecalciferol loading dose, if applicable, and subsequent bimonthly high-dose cholecalciferol through an outreach approach of the Street Doctor Service in Rotterdam. CAU: Care As Usual includes daily prescriptions 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.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria are having a history of alcohol use and currently living in Rotterdam and vicinity.

Exclusion criteria

Exclusion criteria are knee surgery, first year after hip surgery, pregnancy/lactating or trying to conceive, already having vitamin D prescriptions for treatment of osteoporosis or hypovitaminosis 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 [15]: hypercalcaemia, renal failure (glomerular filtration rate <30 mL/min per 1,73m2), history of 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-08-2013
Application type:	First submission

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
NTR-new	NL3949
NTR-old	NTR4114
Other	MEC-2012-273 (METC ErasmusMC), NL40553.078.12; EudraCt: 2012-002207-17 NL 20120502 CTA : Slingedael Korsakovcentrum, Rotterdam
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results