The effect of vitamin D supplementation on vitaminD levels in patients with severe mental illness - a prospective trial

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

Summary

ID

NL-OMON42464

Source
ToetsingOnline

Brief title
VIDEPA-study

Condition

- Vitamin related disorders
- Psychiatric disorders NEC

Synonym
Vitamin D-deficiency / lack of vitamin D

Research involving
Human

Sponsors and support

Primary sponsor: GGz-instelling Yulius
Source(s) of monetary or material Support: Opleidingsbudget;zie ook sectie J

Intervention

Keyword: Cholecalciferol, Deficiency, Severe Mental Ilness, Vitamin D

Outcome measures

Primary outcome

The primary endpoint of this study is an adequate level of vitamin D in at least 80% of the study population after treatment with 800 IU or 1600 IU of vitamin D for 3 months.

Secondary outcome

The main secondary endpoints are: cost-effectiveness of the treatment of all patients with SMI with respect to the treatment of only those patients with a vitamin D deficiency; average increase of the vitamin D levels per100 IU cholecalciferol and the influence of the psychiatric disease on the required amount of vitamin D.

Study description

Background summary

For various reasons, it is important to achieve and maintain appropriate vitamin D levels.Therefore different guidelines advise to treat patients who are at risk for vitamin D deficiency. Although the literature shows that patients with severe mental illness (patients with SMI) also have a higher risk of vitamin D deficiency, this category of patients is not yet included in the risk groups. Furthermore, there is no research in this group of patients on the effective dose of vitamin D to achieve adequate vitamin D levels.

Study objective

The main objective of this study is to investigate if 800 IU or 1600 IU vitamin D is needed to reach adequate levels of vitamin D after 3 months of treatment in at least 80% of the patients with severe mental illness (patients with SMI) between 18 and 70 years (women up to 50 years) and a vitamin D deficiency?

Secondary objectives of the study are:
- Is it cost effective to determine vitamin D levels in all patients with SMI and to treat only those with a vitamin D deficiency or could the treatment be given to all patients with SMI independent of the vitamin D level, for a period of 1 year?
- Is it cost effective to determine vitamin D levels in all patients with SMI and to treat only those with a vitamin D deficiency or could the treatment be given to all patients with SMI independent of the vitamin D level, for a period of 5 years?
- Does the patients psychiatric disease, age, gender, body mass index or smoking status significantly influence the required amount of vitamin D?
- What is the average increase in vitamin D levels in patients with SMI per 100 IU cholecalciferol with a daily oral intake?

Study design

The vitamin D levels of all participants in the study will be measured at baseline. Those with inadequate levels (i.e. <50nmol /L) receive a daily oral dose of 800 IU cholecalciferol. The treatment group will get a new vitamin D measurement after 3 months. When the level is still inadequate, the dosage will be further increased to 1600 IU per day. After another 3 months, there will be one last measurement to determine if an adequate level has been reached.

Intervention

Daily intake of 800 IU cholecalciferol in all patients with inadequate vitamin D levels for 3 months. The dose will be increased to 1600 IU daily for another 3 months if the level is still inadequate after 3 months of treatment with 800 IU daily.

Study burden and risks

The potential risk to the participating patients will be very low.Cholecalciferol is registered for the treatment and prevention of a vitamin D deficiency and has in the applied therapeutic doses (800 IU and 1600 IU) almost no side effects. Very rare side effects are pruritus, rash, and urticaria. It is not likely that the dosage will lead to a toxic level in proper use or other adverse effects. Only those patients with a vitamin D deficiency are treated.
In addition, the number of venipunctures will be limited to a minimum (maximum of 3 venipunctures from 5 ml). The ones that are necessary will be performed simultaneously with another venipuncture where possible, so that the additional burden on patients is limited.

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

- Patients treated by a health care provider from Yulius
- Informed consent
- Severe mental illness (SMI)

Exclusion criteria

- High-Risk patients for vitamin D-deficiency according to the guideline of the Dutch Health Council Contra-indication for vitamin D supplementation
- Use of vitamin D supplementation
- Legally incapable

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	28-07-2015
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
CCMO	NL53568.101.15

Study results

Date completed: 14-04-2017

Actual enrolment: 62

Summary results
Trial is onging in other countries