Does vitamin D deficiency contribute to fatigue in patients in remission after treatment of gynaecological malignancy.

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-To answer the main question *Can we demonstrate a decreased prevalence of fatigue (i.e. a lower score on the fatigue assessment) in patients in complete remission after successful treatment of a gynaecological malignancy, after treatment of a...

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

Summary

ID

NL-OMON35405

Source
ToetsingOnline

Brief title
VItamin D Influence on FATigue In gynaecological MAlignancy (VIDIFATIMA)

Condition

- Other condition
- Reproductive neoplasms male malignant and unspecified

Synonym
Hypovitaminosis D, Vitamin D shortage

Health condition

vitamine D deficiëntie.

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Stichting Bijstand Meander Medisch Centrum Amersfoort

Intervention

Keyword: Fatigue, Gynaecological malignancy, Vitamin D deficiency

Outcome measures

Primary outcome

-Vitamin D level at t=0 and t=2 months.

-Score on fatigue questionnaire at t=0 and t=2 months.

Secondary outcome

Not applicable.

Study description

Background summary

Annually in approximately 4000 women in the Netherlands a gynaecological malignancy is diagnosed. Severe fatigue is a huge problem in a great number of patients who have received treatment because of a gynaecological malignancy. Studies showed that Quality of life is negatively influenced by severe fatigue. Patients treated because of a malignancy are at risk for a vitamin D deficiency due the reduced ability of the older skin to produce vitamin D and decreased exposition to sunlight because of their illness.
Vitamin D deficiency is associated with a range of complaints, such as fatigue, muscle weakness and muscular pains, and an increased risk of fractures. Vitamin D deficiency is easily treated by means of supplementation therapy.
A pilot study of patients treated because of a gynaecological malignancy and diagnosed with a vitamin D deficiency (who visited the outpatients department of the Meander Medical Centre), showed a substantial improvement of their wellbeing after supplementation therapy.

Study objective

-To answer the main question *Can we demonstrate a decreased prevalence of

fatigue (i.e. a lower score on the fatigue assessment) in patients in complete remission after successful treatment of a gynaecological malignancy, after treatment of a vitamin D deficiency with vitamin D supplementation therapy compared to patients treated with a placebo?*

-To answer the secondary question: *Can we demonstrate a decreased prevalence of fatigue (i.e. a lower score on the fatigue assessment) in patients in complete remission after successful treatment of a gynaecological malignancy, by whom an adequate vitamin D level has been diagnosed, after treatment with vitamin D supplementation therapy compared to patients treated with a placebo?*

Study design

Prospective double-blind placebo controlled.

Methods:
-Validated questionaire regarding fatigue and symptoms of a vitamin D deficiency. (t=0 and t= 2 months).
-Blood test to determine the 25-hydroxy vitamine D3 level (t=0 and t= 2 months).
-After randomisation all participating patients will be treated with either Calcium Vitamin D supplementation (100.000 IE, oral) or a placebo (oil-water solubilisation).

Intervention

All participating patients will randomly receive either Calcium Vitamin D supplementation (100.000 IE, oral) or a placebo (oil-water solubilisation).

Study burden and risks

1) Possible side effects of vitamin D supplementation therapy: hypersensitivity is possible, however extremely rare. An overdose of vitamin D (levels > 500nmol/l) may lead to high calcium and phosphate bloodlevels. (due to increased resorption of calcium and phosphate in the intestines and due to bone destruction). We may refer to the paragraph on safety of vitamin D supplementation therapy.
2) Participation in this study, implies twice a bloodtest and twice a questionnaire. The bloodtest is done in the context of the follow-up treatment after a gynaecological malignancy; participation in this study does not require an extra bloodtest.
The questionnaire requires twice some extra time (about 10 minutes) after the appointment at the outpatients department.
3) The vitamin D level is obtained by a venous bloodtest. This is a minimally invasive procedure, and performed by the laboratory of the hospital. Possible side effects might be pain the around the site of needle sting and a small

haematoma is possible.
4) A treatment delay of 2 months is safe for patients with a vitamin D deficiency. It is also safe to prescribe a single dose of 100.000 IE vitamin D to patients with an adequate vitamin D level.

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 in remission after successful treatment of a gynaecological malignancy: ovary carcinoma, endometrial carcinoma, cervical carcinoma, tubal carcinoma or vulva carcinoma who visit the gynaecological oncological outpatients clinic of Meander Medisch Centrum in Amersfoort.;Remission is defined as a disease free status of at least 6 months after termination of the treatment.

Exclusion criteria

-Patients with relapsing disease after initial successful treatment of a gynaecological malignancy.
-Patients with relapsing disease during the study period or within 3 months after inclusion after initial successful treatment of a gynaecological malignancy.
-Patients with renal failure; by definition a MDRD < 60 ml/min, because of the reduced effectiveness of 25(OH)vitamine D.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	292
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cholecalciferol
Generic name:	Vit D AQ
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-11-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-04-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2009-012300-69-NL
CCMO	NL26925.100.09