Efficacy of vitamin D supplementation in preventing peripheral neuropathy in multiple myeloma patients.

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The primary objective of this study is to determine the efficacy of vitamin D supplementation on the severity of PN in patients with multiple myeloma.

Ethical review	Not approved
Status	Will not start
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON43187

Source
ToetsingOnline

Brief title
Efficacy of vitamin D in preventing neuropathy

Condition

- Lymphomas non-Hodgkin's B-cell
- Peripheral neuropathies

Synonym
Peripheral neuropathy; neuralgia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Wetenschapsfonds MCL

Intervention

Keyword: Multiple myeloma, Peripheral neuropathy, Vitamin D

Outcome measures

Primary outcome

The efficacy of vitamin D supplementation on the severity of PN in vitamin D-deficient MM patients with grade 2 or 3 PN. The main endpoint is the percent change in the number of patients whose PN decreases with at least 1 grade.

Secondary outcome

Secondary objectives are to assess an optimal dosing regimen of vitamin D supplementation in MM patients and to search for differences in the effect of vitamin D on PN for each drug.

Study description

Background summary

Randomized controlled trials have shown that the introduction of the novel agents bortezomib, thalidomide and lenalidomide have improved response rates, progression-free survival and overall survival. However, chemotherapy-induced peripheral neuropathy (CIPN), especially when using bortezomib, is a common adverse event. In addition, several studies have found that up to 54% of MM patients have peripheral neuropathy (PN) at diagnosis, indicating that the disease itself can also induce PN. PN decreases quality of life and requires dose adjustment, delay or premature termination of the treatment, resulting in a negative influence on time to progression and survival. Vitamin D was found to reduce polyneuropathy in diabetes mellitus type 2 patients and a possible mechanism was found in animal trials, where the investigators found an increase of nerve growth factor in diabetic rats after supplementation of vitamin D. Recently, it was found that vitamin D deficient MM patients were more likely to have severe CIPN (>grade 2) of both motor and sensory PN and in this study we want to investigate the effect of vitamin D supplementation in MM patients on the occurrence and severity of PN.

Study objective

The primary objective of this study is to determine the efficacy of vitamin D supplementation on the severity of PN in patients with multiple myeloma.

Study design

Patients will be randomized in two groups. Patients in group 1 receive vitamin D supplementation and patients in group 2 will not. The 25-hydroxyvitamin D serum levels of patients in group 1 will be measured after two months, to ascertain a vitamin D level * 75 nmol/l. When necessary, dose adjustments can be made to accomplish an accurate level. After 6 months, vitamin D levels will be determined in all patients. In addition, each patient will complete the self-assessment questionnaire ICPNQ and VAS score after two months and at end of follow-up after six months.

Intervention

Patients in group 1 receive vitamin D-supplements for six months. In addition, every patient will complete the ICPNQ Questionnaire and VAS score after 2 and 6 months to determine neuropathy grading.

Study burden and risks

Preventing CIPN is of great importance for the continuation of chemotherapy and the prolonged exposure presumably results in a higher survival rate and an improved quality of life. As blood sampling is performed frequently in myeloma patients and the questionnaire can be filled in within minutes, the burden for the patients is minimal. Patients do need to take an extra vitamin supplement on top of the other drugs needed for treatment. However, vitamin D in doses in this study is reported a safe intervention without adverse drug reactions.

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 with multiple myeloma with grade 2/3 peripheral neuropathy and a 25-hydroxyvitamin D level <75 nmol/l.

Exclusion criteria

Contraindications for the use of vitamin D and/or patients who are already using any formulation of vitamin D

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Will not start

Enrollment:	52
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	D-Cura 100.000 IE
Generic name:	Cholecalciferol oral solution 100.000 IE
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Divisun
Generic name:	Cholecalciferol
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	19-12-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	EUCTR2016-002343-42-NL
CCMO	NL57872.099.16