Vitamin D status and peripheral neuropathy in multiple myeloma patients

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The primary objective of this study is to determine the correlation between the 25-hydroxyvitamin D serum levels and PN in patients with multiple myeloma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Observational invasive

Summary

ID

NL-OMON45779

Source
ToetsingOnline

Brief title
Vitamin D and peripheral 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 relationship between the occurrence of PN and the vitamin D status in MM patients. The main endpoint is the number of patients with neuropathy and the difference in neuropathy grading between patient groups with or without accurate vitamin D levels.

Secondary outcome

Secondary objectives are to evaluate the influence of different vitamin D levels on the severity of PN; to search for differences in prevalence of PN for each drug; to determine the correspondence of the ICPNQ results and patients' records and to gain insight in the number of patients with inadequate 25-hydroxyvitamin D serum levels (< 75 nmol/l).

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. In this study we want to confirm the relationship of vitamin D status and the occurrence and severity of PN in MM patients.

Study objective

The primary objective of this study is to determine the correlation between the 25-hydroxyvitamin D serum levels and PN in patients with multiple myeloma.

Study design

This is an observational study. Blood samples will be drawn to determine vitamin D levels and the ICPNQ Questionnaire, a validated questionnaire to distinguish different PN grades in MM patients will be completed. VAS scores will be used to grade the intensity of PN.

Study burden and risks

Preventing CIPN is of great importance for the continuation of chemotherapy and a prolonged exposure will presumably result in a higher survival rate and an improved quality of life. When this study confirms the relationship between vitamin D and neuropathy, new opportunities for the prevention of PN may arise. 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.

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

* Subjects are (newly) diagnosed with smoldering or symptomatic MM
* Subjects must be over 18 years of age
* Subjects must be able to give informed consent

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-12-2016

Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	14-11-2016
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	23-08-2017
Application type:	Amendment
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
CCMO	NL58290.099.16