Vitamin D and neuralgia in multiple myeloma

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27690

Source
NTR

Health condition

Peripheral neuropathy - perifere neuropathie
Multiple myeloma - multipel myeloom
Vitamin D - vitamine D

Sponsors and support

Primary sponsor: Medical Centre Leeuwarden
Source(s) of monetary or material Support: Wetenschapsfonds MCL

Intervention

Outcome measures

Primary outcome

The correlation between PN and the vitamin D status in MM patients.

Secondary outcome

- to evaluate the influence of vitamin D on the severity of PN

- to determine the correspondence of the ICPNQ results and patients’ records.

- the number of patients with low 25-hydroxyvitamin D serum levels

- to search for differences in incidence of PN for each drug

Study description

Background summary

Vitamin D status and peripheral neuropathy in multiple myeloma patients

Background: 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.

Objectives: 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. 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 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 population: Patients with smoldering or symptomatic multiple myeloma in the Medical Centre

Leeuwarden are included in the study. Patients must be over 18 years of age and must be able to

give informed consent.

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.

Study objective

Decreased levels of vitamin D is associated with the occurence of peripheral neuropathy in multiple myeloma patients.

Study design

Vitamin D levels and neuropathy grading will be determined at one timepoint.

Intervention

- Blood samples will be drawn to determine 25-hydroxyvitamin D levels.

- All patients will complete the self-assessment survey ICPNQ and when necessary the VAS score, to distinguish different PN grades in MM patients.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with smoldering or symptomatic multiple myeloma

Patients 18 years or older

Able to give informed consent

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	26-09-2016
Enrollment:	120
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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	NL5835
NTR-old	NTR5990
Other	: RTPO 985

Study results