Efficacy of a predefined vitamin D dosing regimen in vitamin D-insufficient multiple myeloma patients.

Published: 14-05-2018
Last updated: 12-04-2024

The primary objective of this study is to determine the efficacy of a predefined vitamin D dosing regimen on the prevalence of vitamin D insufficiency in MM patients. Secondary objectives are to detect the influence of several variables (age, gender...

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

Summary

ID

NL-OMON46493

Source
ToetsingOnline

Brief title
Efficacy of vitamin D supplementation in multiple myeloma patients.

Condition

- Vitamin related disorders
- Plasma cell neoplasms
- Peripheral neuropathies

Synonym
Hypovitaminosis D; vitamin D insufficiency

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 a predefined vitamin D dosing regimen in obtaining an adequate vitamin D level in multiple myeloma patients. The main endpoint is the proportion of patients with an adequate vitamin D level (> 75 nmol/L) after 6 months.

Secondary outcome

Secondary study parameters are: to detect the influence of several variables (age, gender, cumulative dose, type of treatment, race, the use of alcohol and the presence of diabetes mellitus) on the chance of successfully increasing the vitamin D serum concentration; to determine the efficacy of vitamin D supplementation on the prevalence and severity of peripheral neuropathy in multiple myeloma patients; to determine differences between the effect of vitamin D supplementation on the prevalence and severity of PN for each subgroup: treatment, and individual drugs used for MM (drugs that can be used are bortezomib, carfilzomib, daratumumab, elotuzumab, ixazomib, lenalidomide, panobinostat, pomalidomide, thalidomide and vincristine)

Study description

Background summary

Randomized controlled studies have shown that the introduction of the 'new agents' bortezomib, thalidomide and lenalidomide resulted in improved response, progression-free survival and overall survival. However, vitamin D insufficiency is a frequent problem for patients with multiple myeloma. In addition, there is a high prevalence of peripheral neuropathy among these patients. Several studies have shown that an adequate vitamin D level has several advantages for the human body, such as improvement of muscle function and the immune system. Obtaining an adequate vitamin D level in patients with multiple myeloma is therefore a major gain in which the quality of life can improve or decrease less quickly. Vitamin D deficiency is also associated with many complications, such as a decrease in bone density and possibly peripheral neuropathy. This is why we think it is our duty of care to supplement vitamine D-insufficient patients with vitamin D.

Study objective

The primary objective of this study is to determine the efficacy of a predefined vitamin D dosing regimen on the prevalence of vitamin D insufficiency in MM patients.

Secondary objectives are to detect the influence of several variables (age, gender, cumulative dose, type of treatment, race, the use of alcohol and the presence of diabetes mellitus) on the chance of successfully increasing the vitamin D serum concentration; to determine the efficacy of vitamin D supplementation on the prevalence and severity of PN in vitamin D-insufficient MM patients; to determine differences between the effect of vitamin D supplementation on the prevalence and severity of PN for each subgroup: treatment and individual drugs used for MM (drugs that can be used are bortezomib, carfilzomib, daratumumab, elotuzumab, ixazomib, lenalidomide, panobinostat, pomalidomide, thalidomide and vincristine).

Study design

This is an intervention study. Patients who participated in study protocol *Vitamin D status and peripheral neuropathy in multiple myeloma patients* will be screened, and patients who meet the inclusion criteria will be asked to participate in this study. The result of this first study will be used as baseline measurments for the follow-up study if the measurments are not older than 3 months. If they are, a new baseline measurement will be performed. Patients in the study group will receive vitamin D supplementation. The vitamin D serum levels will be measured after two months, to ascertain a vitamin D level > 75 nmol/L. When necessary, another loading dose and dose adjustments can be made to accomplish an accurate level. After 3 months, the vitamin D serum levels will be measured again to ascertain a vitamin D level * 75 nmol/L. If the level does not exceed 75 nmol/L, another dose adjustment will be made. After 6 months, vitamin D levels will be determined in all patients. In

addition, each patient will complete the ICPNQ questionnaire and VAS score after two months and at end of follow-up after six months.

Intervention

Patients receive vitamin D supplements for six months and will receive a vitamin D loading dose no more than twice. In addition, every patient will complete the ICPNQ and VAS score after 2 and 6 months to determine neuropathy grading. After 1, 2, (possibly 3) and 6 months blood samples will be taken. If the baseline measurement is older than 3 months, a new baseline measurement will be performed. This consists of a new blood sample, the ICPNQ and VAS scores.

Study burden and risks

Vitamin D deficiency is associated with many complications, for example a decrease in bone density and possibly peripheral neuropathy. As blood sampling is performed frequently in myeloma patients and the questionnaires can be filled in within minutes, the burden for the patients is minimal. The patients do need to take an extra vitamin supplement in addition to the other drugs needed for treatment. However, vitamin D in doses in this study is reported a safe intervention without adverse drug reactions. The vitamin D tablets are used outside the registered indication, but as the indication has not been restricted due to safety issues of supplementation to patients with vitamin D levels < 75 nmol/L, and a vitamin D level of > 75 nmol/L is considered adequate, we will use 75 nmol/L as the threshold value.

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 multiple myeloma;
Subjects must be over 18 years of age;
Subjects must be able to give informed consent;
Subjects with a vitamin D level * 75 nmol/L.

Exclusion criteria

The use of vitamin D tablets or multivitamin tablets containing vitamin D.
Contraindications for the use of vitamin D:
Hypersensitivity to the active substance(s) or to any of the excipients;
Hypercalcaemia and/or hypercalciuria;
Nephrolithiasis and/or nephrocalcinosis;
Serious renal impairment;
Hypervitaminosis D;
Pseudohypoparathyroidism.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2018
Enrollment:	40
Type:	Actual

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 800 IU tablets
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	14-05-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	14-06-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	31-07-2018
Application type:	Amendment

Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	13-08-2018
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
EudraCT	EUCTR2017-005110-58-NL
CCMO	NL64024.099.17
Other	NTR28251