Vitamin D deficiency in patients with a fracture in the upper or lower extremity: a monocenter cross-sectional study

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In the present study the prevalence of and risk factors for vitamin D deficiency will be determined in a patient population with a fracture in the upper or lower extremity.

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

Summary

ID

NL-OMON37454

Source
ToetsingOnline

Brief title
Vitamin D deficiency in fracture patients

Condition

- Other condition
- Fractures

Synonym
shortage of vitamin D, Vitamin D deficiency

Health condition

Endocrien, vitamine D

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fracture healing, Vitamin D deficiency

Outcome measures

Primary outcome

Vitamin D deficiency, defined as calcidiol serum concentration < 50nmol/L,

according to international standards.

Secondary outcome

Exposure to ultraviolet radiation: measured in number of hours of exposure to

UV radiation per week.

Blood serum: Calcium, Albumin, phosphate and renal function (MDRD)

Study description

Background summary

A large part of the western population has a vitamin D deficiency, but is unaware of this condition. Vitamin D deficiency is not only common among the adult population, also half of the young people are vitamin D deficient. Vitamin D plays an important role in bone mineralization and during the different stages of fracture healing. There is, however, a lack of data on prevalence of and risk factors for vitamin D deficiency in the relatively young population of patients with a fracture caused by trauma. For this reason, the vitamin D serum concentration of fracture patients in the LUMC will be determined.

Study objective

In the present study the prevalence of and risk factors for vitamin D deficiency will be determined in a patient population with a fracture in the

upper or lower extremity.

Study design

A monocenter cross-sectional study

Study burden and risks

A total of 35cc blood will be taken from all patients, involving only minor health risks. Also each patient will fill out a questionnaire (15min).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Fracture of the upper or lower extremity, including the shoulder and hip.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	1250
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	26-07-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	23-08-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL38909.058.12