

The Effect of Vitamin D status on Fracture healing - a prospective cohort study

Published: 15-04-2015

Last updated: 19-04-2024

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

Summary

ID

NL-OMON42821

Source

ToetsingOnline

Brief title

Vitamin D status and fracture healing

Condition

- Fractures

Synonym

Fracture healing; delayed union

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Afdelingsfonds Trauma

Intervention

Keyword: Consolidation, Fracture healing, Vitamin D

Outcome measures

Primary outcome

Delayed union, defined as incomplete consolidation (clinically and radiologically) after 4 months.

Secondary outcome

- Non-union, defined as absent fracture consolidation after 9 months
- Complications during fracture healing (infection, mal-Union, refracture, (re)operation).
- Perceived pain
- Functional recovery
- Quality of life
- Costs.
- Natrium, potasium, kreatinin, calcium, fosfor, PTH, alkaline phosphatase, CTX en PINP

Study description

Background summary

A large part of the population has a relative or absolute vitamin D deficiency. Recent unpublished results show that 70% of the patient population between 18 and 50 years with a fracture has a vitamin D insufficiency (25 (OH) D <75 nmol / L), and 40% has a deficiency (25 (OH) D <50 nmol / L). Vitamin D plays an important role in the cellular process of fracture healing. However, the number of available clinical studies on the role of vitamin D on fracture healing is scarce and these studies mainly focus on elderly fracture patients. The clinical effect of vitamin D status and vitamin D supplementation on fracture

healing is unknown in the fracture population aged between 18 and 50 years.

Study objective

The influence of the initial vitamin D status on the fracture consolidation will be studied. These study results might give rise to a randomised controlled trial with vitamin D supplementation in order to investigate the effect of supplementation on fracture healing. Primarily, the effect of vitamin D status on bone healing, the incidence of delayed fracture healing (delayed union) will be investigated. Secondary the effect of vitamin D status on the occurrence of complications, functional outcome, and health-related quality of life will be investigated. We will also examine the influence of the initial vitamin D status on the fracture healing, and conduct a costanalysis on vitamin D status.

Study design

In this prospective cohort study, patients will be seen according to a fixed schedule during which fracture healing will be monitored using radiography, and blood samples will be obtained for determination of the vitamin D status and biomarkers for fracture healing.

Study burden and risks

Participation in the study involves more time for the patient (1-2 additional visits to the outpatient clinic, filling out questionnaires). Also blood samples will be obtained three times during the study. The X-rays investigations are standard treatment practice. The risk of participation is minimal since it is a relatively young patient population, in whom normally vitamin D is not determined or administered.

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

- Age 18 -50 years
- Extra-articular fracture of the clavicle, humerus, fore arm, metacarpalia, femur, lower leg or metatarsalia.
- Initial X-ray;s
- Inclusion within 10 days after trauma

Exclusion criteria

Refracture, pathological fracture, complicated fracture.

Use of vitamin D or glucocorticosteroids

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):	28-08-2015
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO	
Date:	15-04-2015
Application type:	First submission
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	NL52965.058.15