The Effect of Vitamin D on the Consolidation of Extra-articular Fractures - a double-blind randomized controlled trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20608

Source
Nationaal Trial Register

Brief title
D-Union

Health condition

Vitamin D; Vitamin D deficiency; Vitamin D insufficiency; Vitamin D supplementation; Fracture healing; Delayed union.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: -

Intervention

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
- Cost(effectiveness)

Study description

Background summary

Background:
A large part of the population has a relative or absolute vitamin D deficiency. Recent, as yet unpublished results show that 70% of the patient population between 18 and 50 years with a fracture has a vitamin D insufficiency (25 (OH) D 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 a 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 objectives:
The influence of the initial vitamin D status and the effect of vitamin D supplementation on the fracture consolidation will be studied. An evidence-based recommendation to vitamin D status and vitamin D supplementation in fracture treatment will be based on the study results. Primarily, the effect of vitamin D supplementation on bone healing, the incidence of delayed fracture healing (delayed union) will be investigated in a vitamin D insufficient fracture population. Secondary the effect of vitamin D supplementation 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 cost-effectiveness analysis on vitamin D supplementation.

Study design:
In this double-blind randomized controlled trial, patients are randomized between 25.000IU Colecalciferol once a month for 4 months and placebo once a month for 4 months. 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.

Study population:
250 patients aged between 18 and 50 years, with an extra-articular fracture of a long bone (clavicle, humerus, radius, antebrachii, femur, tibia, cruris or Weber A, B or C fracture).

Study objective

Vitamin D supplementation reduces the incidence of delayed union in fracture patients with a vitamin D insufficiency, compared to placebo.

Study design

1, 4, 8, 12, 16, 26 and 52 weeks after fracture.

Intervention

Group studie medication:
25.000IU Colecalciferol once a month during a period of 4 months.

Group placebo:
Placebo once a month during a period of 4 months.

Contacts

Public
PO-box 9600
I.B. Schipper
Leiden University Medical Center
Department of Surgery - Traumatology D6-18
Leiden 2300 RC
The Netherlands
+31 (0)71 5264005
Scientific
PO-box 9600
I.B. Schipper
Leiden University Medical Center
Department of Surgery - Traumatology D6-18
Leiden 2300 RC
The Netherlands
+31 (0)71 5264005

Eligibility criteria

Inclusion criteria

- Age between 18 and 50 years
- Extra-articular fracture of a long bone (clavicle, humerus, radius, antebrachii, femur, tibia, cruris or Weber A, B or C fracture)

Exclusion criteria

- Refracture; pathologic fracture; complicated fracture; Injury severity Score > 16; pregnancy
- Growth hormone deficiency; Immune compromised, sarcoïdosis
- Use of: Vitamin D, corticosteroids, digoxin, calcium / bisfosfonate, phenobarbital, phenytoïn

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2014
Enrollment:	250
Type:	Anticipated

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	NL4236
NTR-old	NTR4381
Other	: 45897

Study results

Summary results
NA