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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20608

Bron
Nationaal Trial Register

Verkorte titel
D-Union

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 Recent, as yet unpublished results show that 70% of the patient population between 18 and 50 years with a fracture has a vitamin D insufficiency (25 (OH) D 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).

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4236
NTR-old	NTR4381
Ander register	: 45897

Resultaten

Samenvatting resultaten
NA