Prediction of non-union in diaphyseal fractures

Published: 30-11-2017
Last updated: 13-04-2024

Based on the risk-factors a prediction model for non-union will be developed. Also the effect of a initial vitamin D deficiency on fracture healing will be investigated.

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

Summary

ID

NL-OMON47158

Source
ToetsingOnline

Brief title
Non-union prediction model

Condition

- Fractures

Synonym
Delayed fracture healing

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Onderzoeksfonds Traumachirurgie LUMC

Intervention

Keyword: Delayed union, Diaphyseal fractures, Non-union, Risk factors

Outcome measures

Primary outcome

The primary study parameter is non union, defined as no full consolidated fracture after 9 months or in case additional surgery has been performed earlier due to insufficient fracture healing.

Secondary outcome

Investigate the effect of vitamin D status / deficiency on fracture healing; on the development of delayed or non-union.

Study description

Background summary

Delayed-union or non-union is a complication during fracture healing which is associated with prolonged fracture treatment and often requires additional therapy. The incidence of non-union is around 10%. In literature several risk-factors are identified, in whereby the effect of vitamin D deficiency is relative unknown. Although these risk-factors are known, no prediction model has been developed in order to identify the fractures at risk for delayed or non union. A prediction model allows clinician to interfere early in fracture treatment in order to prevent prolonged follow up, additional treatment with de accompanied negative consequences for the patient.

Study objective

Based on the risk-factors a prediction model for non-union will be developed. Also the effect of a initial vitamin D deficiency on fracture healing will be investigated.

Study design

Prospective cohort investigation in 3 level 1 trauma centra.

Study burden and risks

Participation in the study involves filling out a questionnaire (5-10 minutes)

once, and obtaining a blood sample once. There are minimal risks associated with the vena puncture.

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 18-70 years
Diaphyseal fractures of the clavicle, humerus, fore-arm, femur or lower leg.
Initial trauma X-rays available.

Exclusion criteria

- Re-fracture; pathological fracture, more than one diaphyseal fracture
- Additional injury with an abbreviated Injury Scale (AIS) grade * 2

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2018
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-06-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60175.058.17

Study results

Date completed: 30-10-2019

Actual enrolment: 100

Summary results
Trial ended prematurely