Detection of biomarkers for delayed fracture healing: A retrospective multicentre cohort study

Published: 31-08-2011 Last updated: 04-05-2024

The aim of this project is to determine the possible use of biomarkers for non- or delayedunion in fractures of the diaphyseal femur and tibia.

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

Summary

ID

NL-OMON36380

Source ToetsingOnline

Brief title Biomarkers for delayed fracture healing

Condition

• Fractures

Synonym bone repair, fracture healing

Research involving Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum Source(s) of monetary or material Support: subsidie in aanvraag

Intervention

Keyword: biomarker, bone union, fracture, healing

Outcome measures

Primary outcome

Circulating levels and corresponding genetic variations of biomarkers are the

primary parameters.

These are compared between patients with normal union and delayed-union.

Secondary outcome

not applicable.

Study description

Background summary

After the occurrence of a bone fracture, a significant percentage will heal within 9 months, the standard time span for fracture healing. However, 5-30% of fractures will show delayed or non-union. Numerous proteins play a significant role in bone regeneration, fracture healing and wound healing. Abnormal circulating levels of these proteins may be associated with the development of non- or delayed union. Systemic alterations of these proteins which are detectable in the circulation may serve as biological markers (biomarker) for the extent and prognosis of fracture healing. Genetic mutations could cause the impaired expression of proteins leading to abnormal circulating levels.

Study objective

The aim of this project is to determine the possible use of biomarkers for nonor delayed-union in fractures of the diaphyseal femur and tibia.

Study design

Retrospective, multicentre, cohort study.

Study burden and risks

A total amount of 28.5 ml blood per patient will be drawn once.

Contacts

Public Leids Universitair Medisch Centrum

Albinusdreef 2 2333 ZA Leiden NL **Scientific** Leids Universitair Medisch Centrum

Albinusdreef 2 2333 ZA Leiden NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Diaphyseal fracture of the tibeal or femoral bone

Exclusion criteria

Legal incapacity No informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2011
Enrollment:	200
Туре:	Actual

Ethics review

Approved WMO Date:	31-08-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	04-11-2011
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.

4 - Detection of biomarkers for delayed fracture healing: A retrospective multicentr ... 24-05-2025

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

ССМО

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