Detection of biomarkers for impaired fracture healing: A prospective multicentre cohort study

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The aim of this project is to determine the possible use of biomarkers for non or delayed union in long bone fractures of the diaphyseal femur and tibia.

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

Summary

ID

NL-OMON36740

Source
ToetsingOnline

Brief title
Biomarkers for impaired 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: biomarkers, bone, fracture, healing, union

Outcome measures

Primary outcome

Circulating levels and genetic variations of biomarkers are considered to be

the effect variables. Outcome variables are physiological fracture healing and

impaired fracture healing (delayed and non union).

Secondary outcome

not applicable

Study description

Background summary

Fracture healing is a unique and complex repair process. However, impaired fracture healing remains a common problem and its pathophysiology is poorly understood. Plain radiography and CT scans remain the standard method of monitoring fracture healing, but it documents impaired healing only late in the course. Depending on several factors 5-30% of fractures will fail to heal adequately. Numerous proteins have been described having a significant role in bone regeneration, fracture healing and wound healing. An abnormal expression or abnormal circulating levels of these proteins could possibly be associated with the development of non- or delayed union. Systemic alterations of these proteins are detectable in the circulation and can therefore serve as a biological marker (biomarker) for the prognosis and the extent of fracture healing. Secondly, it is possible that genetic mutations impair the expressions of these proteins leading to abnormal circulating levels. Early detection of impaired expression of these parameters could lead to personalized treatment of the patients.

Study objective

The aim of this project is to determine the possible use of biomarkers for non or delayed union in long bone fractures of the diaphyseal femur and tibia.

Study design

Observational prospective multicentre cohort study.
Protein levels and the genetic variations causing the systemic alterations will be determined.

Study burden and risks

From all participating patients a total of 6 peripheral blood samples will be collected. The logistic burden associated with participation will be minimal because 5 of the 6 bloodsamples will be collected during standard follow up procedures at the outpatient department. Only the final and 6th blood sample will not be combined with a checkup at the outpatient department. Radiographs, other research investigations or the nature of the physical examination or interview will be according to the standard treatment management.

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

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:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	425
Type:	Actual

Ethics review

Approved WMO

Date:	21-02-2011
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	NL31514.058.10