

Medical Aspects of Implant Removal after Osteosynthesis

Published: 02-04-2007

Last updated: 15-05-2024

nvt

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

Summary

ID

NL-OMON33611

Source

ToetsingOnline

Brief title

the Implant Removal Trial

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym

metal removal

Research involving

Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis

Source(s) of monetary or material Support: niet van toepassing eigen budget

Intervention

Keyword: implant, osteosynthesis, removal

Outcome measures

Primary outcome

nvt

Secondary outcome

nvt

Study description

Background summary

nvt

Study objective

nvt

Study design

nvt

Study burden and risks

nvt

Contacts

Public

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NL

Scientific

Amphia Ziekenhuis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

18 years of age and older

consolidated fracture at least one year old

informed consent

plate or nail osteosynthesis (clavicle, ulna, radius, femur, tibia)

Exclusion criteria

younger than 18 years

a fracture that isn't healed

implants on an other location as mentioned in the inclusion criteria

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 17-09-2007
Enrollment: 300
Type: Actual

Ethics review

Approved WMO
Date: 02-04-2007
Application type: First submission
Review commission: METC Brabant (Tilburg)
Approved WMO
Date: 19-03-2008
Application type: Amendment
Review commission: METC Brabant (Tilburg)
Approved WMO
Date: 22-01-2010
Application type: Amendment
Review commission: METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27207
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL15133.008.07
OMON	NL-OMON27207