ROutine versus on DEmand removal Of the syndesmotic stabilisation screw; a randomized controlled trial (RODEO-trial)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20095

Source
Nationaal Trial Register

Brief title
RODEO-trial

Health condition

Ankle/Enkel
Fracture/Fractuur
Syndesmotic screw/Syndesmose schroef
Implant removal/ Verwijderen osteosynthesemateriaal
Routine removal/ Routinematig verwijderen schroef
Removal on demand/ op indicatie verwijderen schroef
Functional outcome/ functioneel herstel
Cost-effectiveness/ kosteneffectiviteit

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

OMAS

Secondary outcome

• Functional outcome through the American Orthopedic Foot and Ankle Score (AOFAS)

• Pain though the Visual analog scale (VAS-score)

• Range-of-motion

• Surgical complications (such as wound infections)

• Recurrent syndesmotic diastasis

• Quality of life though the EQ-5D-5L

• Health care consumption through the iMCQ

• Loss of productivity through the iPCQ

Study description

Background summary

The RODEO trial investigated the difference in functional outcome between routine and on demand removal of the syndesmotic screw and found that on demand removal was non-inferior to routine removal.

Study objective

The outcome in patients with removal on demand is not inferior to the outcome in patients with routine removal. By omitting routine removal a reduction in costs will be achieved

Study design

3, 6 and 12 months postoperatively

Intervention

We will investigate a removal on demand strategy regarding the syndesmotic screw. This means that patients, in whom a syndesmotic screw has been placed, will not be scheduled for screw removal unless the screw becomes symptomatic. Examples of symptomatic hardware are restricted range-of-motion and prominent screws.

Contacts

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Eligibility criteria

Inclusion criteria

• Over 17 years of age

• A syndesmotic screw for an instable ankle fracture

• Syndesmotic screw placed within two weeks of the trauma

• Being in such condition that one is able to possibly undergo a second procedure

Exclusion criteria

• Patients treated with another device than a syndesmotic screw

• ISS score > 15

• Injuries to the ipsi- and contralateral side which might hamper rehabilitation

• Other medical conditions which hamper physical rehabilitation

• Incomprehensive understanding of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	196
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
on request

Ethics review

Positive opinion

Date:	15-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47890
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5810
NTR-old	NTR5965
CCMO	NL58539.018.16
OMON	NL-OMON47890

Study results

Summary results
submitted