ROutine versus on DEmand removal Of the syndesmotic stabilisation screw; a randomized controlled trial

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Primary Objective: To demonstrate that a on demand removal strategy of the syndesmotic positioning screw is non-inferior in functional outcome compared with routine removal of the syndesmotic positioning screw. Secondary Objective(s): We aim to...

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

Summary

ID

NL-OMON47890

Source
ToetsingOnline

Brief title
RODEO-trial

Condition

- Fractures

Synonym
Ankle fracture, Syndesmotic injuries

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: On demand, Routine, Syndesmosis, Syndesmotic screw

Outcome measures

Primary outcome

Olerud Molander score

Secondary outcome

AOFAS

VAS score

Surgical complications

Recurrent syndesmotic diastasis

Quality of Life

Health care consumption

Loss of productivity

Study description

Background summary

Ankle fractures are among the most common fractures. It is estimated that more than 25000 people suffer from an ankle
fracture in the Netherlands annually and the incidence is rising. Both young and elderly people are at risk for these fractures.
In general younger people are more at risk as a result of a more active lifestyle and elderly people because of poorer bone
quality. Approximately half of the patients with an ankle fracture require surgical treatment because of joint instability. In
approximately 20% of these fractures there is a concomitant injury of the syndesmosis and syndesmotic repair is indicated. A
syndesmotic *positioning screw* is placed through the fibula into the tibia to assure stability and allow the syndesmotic
ligaments to heal. Elaborate research has been conducted regarding the technical aspects of the placement of the syndesmotic

screw. For example, the number of required screws, its diameter, level of placement and whether it should engage three or four cortices has been investigated thoroughly.
After a period of 8 * 10 weeks the syndesmosis will be healed and the screw will lose its function. It is an ongoing discussion whether the syndesmotic screw needs to be removed subsequently. Most surgeons advocate its removal because of suspected impaired range of motion and chance of breakage of the screw. During normal ambulation the fibula moves and the syndesmosis widens. The positioning screw is thought to restrict this movement and the screw is therefore removed after 8 * 12 weeks. However, several case series have shown similar outcomes in patients in which the syndesmotic screw was retained compared to patient in whom the syndesmotic screw was removed. The positioning screw is most likely not causing complaints in patients with retained screws because of loosening or breakage of the screw. Currently there is not enough evidence for neither routine removal and removal on demand, providing such evidence is desirable for both physicians and patients

Study objective

Primary Objective: To demonstrate that a on demand removal strategy of the syndesmotic positioning screw is non-inferior in functional outcome compared with routine removal of the syndesmotic positioning screw.

Secondary Objective(s): We aim to compare ankle function and amount of adverse events between the two treatment strategies. Lastly, we intent to investigate the socio-economic impact of our intervention.

Study design

The study will be a pragmatic, multicenter randomized controlled non-inferiority trial. The study will compare a removal on demand strategy with a routine removal strategy regarding the syndesmotic screw. We will advocate a preferred method of fixating the syndesmosis (i.e. one 3,5 mm screw through 3 cortices). However, the pragmatic design means that the final decision technical details regarding the placement of the screw (e.g. number of screw(s), size of the screw(s) and number of cortices engaged) are left at the discretion of the operating surgeon. In total the duration of the study will be three years. Inclusion will take approximately two years and the follow-up lasts one year. An overview of the study is shown in figure 1. The follow-up moments will take place 3, 6 and 12 months following surgery for the ankle fracture.

Intervention

On demand removal of the syndesmotic screw, removal is only performed in case of symptomatic hardware such as painful
hardware or hardware (supposedly) causing restricted range of motion

Study burden and risks

The risks in this study are acceptable for the patients participating in this study as both treatment options are well-known and safe, furthermore are they both part of daily practice. Furthermore, no extra visits or longer follow-up are required for the study.

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

* 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2017
Enrollment:	183
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2017

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 20095
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58539.018.16
OMON	NL-OMON20095