

Fixation of the posterior malleolus via the posterolateral or precutaneous "AP" approach, an analysis of radiological and functional outcome.

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To compare radiological and functional outcome in 2 retrospective cohorts. We compare the results of the MILAN study with a cohort after changing our operative strategy in 2010.

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

Summary

ID

NL-OMON43896

Source

ToetsingOnline

Brief title

POSTAP

Condition

- Fractures

Synonym

ankle fracture, Trimalleolar fracture

Research involving

Human

Sponsors and support

Primary sponsor: MCH en Bronovo-Nebo

Source(s) of monetary or material Support: Landsteiner Instituut MCHaaglanden

Intervention

Keyword: Internal fixation., posterolateral approach, Trimalleolar fracture

Outcome measures

Primary outcome

Functional outcome will be evaluated by AAOS- (and AOFAS)-questionnaires. Both questionnaires are developed for ankle and foot problems only. Additionally, the VAS-pain is taken and a functional range of motion test of the injured and contralateral ankle is taken.

Secondary outcome

Osteoarthritis will be measured on X-ray according to the Kellgren-Lawrence scale.

Study description

Background summary

The optimal treatment in trimalleolar fractures remain unclear. Especially, if and how a posterior malleolar fracture needs to be fixed. Five years ago, a posterior malleolar fracture was fixed by percutaneous antero-posterior screw fixation. Nowadays, the posterior malleolar fracture is fixed by a posterolateral approach which leads to a direct and anatomical reposition. It remains unclear if these theoretical advantages leads to a better functional and radiological outcome.

Study objective

To compare radiological and functional outcome in 2 retrospective cohorts. We compare the results of the MILAN study with a cohort after changing our operative strategy in 2010.

Study design

All patients with operative fixation of a trimalleolar fracture between Januar 1st 2011 and December 31st 2013 will be invited to visit the outpatient clinic

for X-ray of the ankle, questionnaires and a functional test. Outcome of these patients will be compared with another cohort which was invited earlier (MILAN-study) with almost the same follow-up period.

Study burden and risks

Compared with the yearly dose of background radiation the additional radiation doser of 1 X-ray is such low that this risk is negligible according to the investigators.

Contacts

Public

MCH en Bronovo-Nebo

Lijnbaan 32
Den Haag 2512VA
NL

Scientific

MCH en Bronovo-Nebo

Lijnbaan 32
Den Haag 2512VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

>18 years old at time of trauma and <75 years old at time of follow-up
Open reduction and Internal Fixation of trimalleolar fracture

Exclusion criteria

History of ankle fracture.
Pre-existent impairment in mobility
Inability to speak the Dutch language.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Date:	18-03-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL55397.098.15