Rotational malalignment of the lower leg after intramedullary osteosynthesis (ROMIO).

Published: 27-02-2009
Last updated: 06-05-2024

Is the present malrotation of the tibia, 15 degrees exorotation and 10 degrees endorotation, after intramedullary nailing acceptabel. Furthermore, we want to know which technique could reduce the possible malalignment in patients. In present there...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON33674

Source
ToetsingOnline

Brief title
ROMIO

Condition

- Fractures

Synonym
1)maltorsion 2)malrotation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Anna Fonds;NutsOhra en AO foundation

Intervention

Keyword: cruris fracture, intramedullary nailing, rotational malalignment, tibia

Outcome measures

Primary outcome

A validated and acceptated limit in rotational malalignment.

Secondary outcome

* incidence of malrotation

* correlation between the amount of malrotation and the presence of knee or

ankle arthritis and clinical experience

* validated and reliable clinical assessment compared with CT measurement

* malrotation between both oepration techniques

Study description

Background summary

When patients with a cruris fracture are treated with intramedullaire nailing it is possible that a rotational malalignment could occur. Rotational malaligment could lead to earlier onset of osteoarthritis on long term. On short term patellofemoral complaints and gait changes are possible. The incidence of rotational malalignment is unknown and this is partly due to the fact that there is no consensus in the deviation that is acceptable for patients.

Study objective

Is the present malrotation of the tibia, 15 degrees exorotation and 10 degrees endorotation, after intramedullary nailing acceptabel. Furthermore, we want to know which technique could reduce the possible malalignment in patients. In present there are two standard techniques used during operation; free hand technique and the fixation technique.

Study design

The research is divided in two parts; retrospective long term follow-up study and a prospective, randomised study to compare the two oepration techniques.
ROMIO I (retrospective):
CT-scan, questionnaires and clinical evaluation
The clinical evaluation will be done by three observers at several time points. With this procedure we can also evaluate the intra- and interobserver variation.
ROMIO II (prospective):
randomisation in free hand technique or extension/traction table technique
The follow-up of patients will be done on standard time points, with a complementary CT-scan at 3 months postoperative. During these follow-up moments questionnaires and clinical evaluation will be done by each patient.

Intervention

The ROMIO II group has an intervention in terms of operation technique. The differences in the group are pending on the so called 'free hand' technique and extension/traction technique.

Study burden and risks

Patients in the ROMIO I part will have to visit the clinic again, becasue standard follow-up is already ended.
ROMIO II patients have no advantage and disadvantage of participation in the study. A extra CT scan is the extra burden that will be done at 3 months postoperative.

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

- crurisfracture where operative treatment is necessary with a UTN
- age > 18 years

Exclusion criteria

- Multi trauma, wit h more fractures such as
ipsilaterl pilon fracture
lateral or medial malleolus fracture
syndesmose rupture
- reumatic arthritis
- poly arthritis
- no dutch language mastered
- pregnancy or desired to be pregnant

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	230
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-02-2009
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	NL23628.098.08