

Revision surgery (for proximal tibia and) for tibia plateau fractures.

Published: 07-01-2014

Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON41685

Source

ToetsingOnline

Brief title

Revision TPF

Condition

- Bone and joint therapeutic procedures

Synonym

Knee fractures, tibiaplateau fractures osteosynthese revision

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fracture, revision, tibia

Outcome measures

Primary outcome

The main study parameters are the outcomes of the Dutch Version of the International Knee Documentation Committee Subjective Knee questionnaire. Using conventional x-ray we will be able to see and document the consolidation progress and post-traumatic arthrosis throughout the period of follow up. To evaluate varus or valgus deformity, a leg-axis conventional x-ray will be made.

Secondary outcome

nvt

Study description

Background summary

Tibia plateau fractures usually arise from high impact traumas such as motorcycle accidents or a fall from large height. The most common used classification used in tibia plateau fractures is that of Joseph Schatzker. Ranging from 1-6, it differentiates between split fractures, depression fractures, shaft fractures, the localization (medial/lateral) or a combination of the above. The optimal form of treatment is still a subject of debate and there are several prognostic factors named to predict long term functional and radiological results: fracture type, degree of post traumatic arthrosis, degree of remaining incongruence and the recovery of the leg axis. In order to create sustainable long term functionality of the knee joint after a tibia plateau fracture, one could argue that stable fixation and anatomical reposition are of the utmost importance. In the recent past the long term outcome of all tibia plateau fractures treated operatively in the AMC were reported (ref. M. Rademakers et al.)

Although a large segment of the patients treated for a tibia plateau fracture have a relatively uneventful recovery, a small percentage has to cope with complications resulting from the often challenging surgery. There are a number of articles written on several complications that may arise after surgical

management, but the clinical results of revisional surgery that takes place in specialized centres remains underexposed.

Study objective

The primary objective of the study is to determine the patient satisfaction and assess objectively the clinical outcome. The secondary objective is to determine whether the revision surgery after mal/non-union of the tibial plateau fracture was successful and fully consolidation was achieved.

Study design

This study is designed as a retrospective study with postoperative follow- up.

Study burden and risks

All patients will receive three conventional X-rays of the knee, which is an exposure to radiation. This study does not provide immediate advantage for the participating patient.

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

Revisional surgery after osteosynthese for tibialplateau fracture

Exclusion criteria

primaire osteosyntheses for tibialplateau fracture

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-01-2014

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 07-01-2014

Application type: First submission

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	NL44673.018.13