Effect of transverse versus longitudinal incisions and suprapatellar approach on anterior knee pain after tibial nailing; a multicenter randomized trial

Published: 15-10-2014
Last updated: 21-04-2024

The aim of this prospective, multicenter, trial is 1) to describe the effect of a suprapatellar approach on anterior knee pain, and 2) to assess the effect of a transverse versus a longitudinal transpatellar incision on anterior knee pain.

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

Summary

ID

NL-OMON44985

Source
ToetsingOnline

Brief title
TRAVEL study

Condition

- Fractures

Synonym
anterior knee pain

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC

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

Intervention

Keyword: anterior knee pain, incision, suprapatellar approach, tibial nailing

Outcome measures

Primary outcome

Primary outcome measure for the randomized trial is the difference in kneeling pain based on a numeric rating scale (NRS) at 12 months post-surgery between patients treated with a longitudinal and a transverse incision.

Secondary outcome

Secondary outcome measures for the randomized trial (transverse versus longitudinal incision) include differences at 12 months post-surgery between both groups for knee pain during daily activities, infrapatellar nerve injury, functional outcome and health care consumption. Outcome measures for the cohort study (suprapatellar approach) include all above mentioned parameters.

Study description

Background summary

Anterior knee pain is a common complaint after intramedullary nailing of the tibia. Iatrogenic injury to the infrapatellar nerve is thought to be a contributing cause in the trans- and parapatellar approach. The recently introduced suprapatellar approach has proven feasible, but only limited data exists on its effect on knee pain. We hypothesize that anterior knee pain after tibial nailing can be reduced by decreasing the risk of infrapatellar nerve injury.

Study objective

The aim of this prospective, multicenter, trial is 1) to describe the effect of a suprapatellar approach on anterior knee pain, and 2) to assess the effect of

a transverse versus a longitudinal transpatellar incision on anterior knee pain.

Study design

The study is divided in two parts. Part A (cohort): patients will be treated with a suprapatellar approach if the fracture is suitable for this technique and if the treating surgeon is familiar with it. Few patients are expected to be treated using this approach and therefore will be analysed separately. Part B (randomized trial): all other eligible patients will be treated with the transpatellar approach and will be equally randomized to a longitudinal or transverse incision. A total of 120 patients will be included in Part B.

Intervention

Patients treated with a transpatellar approach will be equally randomized to a longitudinal or transverse incision.

Study burden and risks

All patients will be reviewed at the outpatient clinic by the treating surgeon and a research assistant at 2 weeks post-surgery and at 6 weeks, 3, 6 and 12 months post-surgery. Depending on the time since surgery the time-specific questionnaires will be completed (one pain questionnaire, two functional outcome questionnaires, one questionnaire about general well-being and one about healthcare consumption). Radiographs are a standard of care and will be taken before every visit in order to check nail position and radiographic union. Except for a possible diminished chance of anterior knee pain in the transverse group no benefits are expected for participants. No extra risks are accounted for when participating in this study. A large proportion of tibia shaft fractures is due to sports (soccer) and traffic accidents (scooter, bicycle etc). This group is mainly represented by young males. Therefore this specific age group (16-17) is included in the study.

Contacts

Public
Erasmus MC

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age between 16 and 65 years
Unilateral tibial shaft fracture (AO 42 A, B and C)
Indication for intramedullary nailing in judgement of the treating surgeon (within 2 weeks after initial trauma)
Provided written informed consent by patient

Exclusion criteria

Gustilo open fractures grade III-C or open wound on knee
Polytrauma patients, when concurring injury affect treatment and recovery
Patients with bilateral tibial shaft fractures
Patients with a pathological or recurrent fracture of the tibia
Patients with pre-existing knee pathology (e.g. menisci, cruciate ligament)
Patients with pre-existing functional impairment which has influence on rehabilitation (e.g. wheelchair-bound)
Patients with rheumatoid arthritis
Patients with bone disease resulting in delayed union (except osteoporosis)
Insufficient comprehension of Dutch language to adhere to treatment guidelines
Likely problems with follow-up (e.g. no fixed address)

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):	06-09-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	20-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL49144.078.14