Effect of Transverse versus Longitudinal Incisions on Anterior Knee Pain after Tibial Nailing (TRAVEL); a multicenter randomized trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23839

Source
NTR

Brief title
TRAVEL

Health condition

Tibia shaft fractures

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Trauma Research Unit, Department of Surgery
Erasmus Medical Center, Medical Research Ethics Committee (MREC)
Source(s) of monetary or material Support: AO Research Foundation, Switzerland

Intervention

Outcome measures

Primary outcome

Kneeling pain (Numeric Rating Scale)

Secondary outcome

Knee pain scores (NRS) for specific daily activities (including running, walking, jumping, stair climbing, squatting, sitting with flexed knees, and cycling); Functional outcome and health-related quality of life (SMFA and LEFS); Time to return to daily activities and work; Costs for health care and production losses; Range of motion of the knee and ankle; Nail prominence; Rate of complications; Rate of secondary interventions; Cosmesis (5-point scale); Cost-effectiveness

Study description

Background summary

BACKGROUND

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. We hypothesize that anterior knee pain after tibial nailing can be reduced by decreasing the risk of infrapatellar nerve injury.

AIM

The primary aim of this prospective, multicenter, trial is to assess the effect of a transverse versus a longitudinal transpatellar incision on anterior knee pain. Secondary aims are to assess the effect on functional outcome, pain during specific activities, health-related quality of life, ROM, complications, and cosmesis in these patients. The costs and cost-effectiveness of both interventions will be determined.

STUDY DESIGN

Multi-center randomized controlled trial. Approximately 10 hospitals in the Netherlands will participate.

POPULATION

Patients between 16 and 65 years of age with a tibial shaft fracture amenable to surgical

treatment with an intramedullary nail are eligible.

INTERVENTIONS

Patients treated with a transpatellar approach will be equally randomized to a longitudinal or transverse incision. Critical elements of the operation will be recorded but not standardized. Due to a lack of evidence favoring a particular approach, the physical therapy and rehabilitation program will be recorded but not standardized. This allows for post-hoc analysis and improves generalization of the study results.

ENDPOINTS

Primary outcome measure: kneeling pain based on a numeric rating scale (NRS) at 12 months post surgery
Secondary outcome measures: Knee pain scores (NRS) for daily activities; Functional outcome and health-related quality of life (SMFA and LEFS); Time to return to daily activities and work; Costs for health care and production losses; Range of motion of the knee and ankle; Nail prominence; Rate of complications; Rate of secondary interventions; Cosmesis (5-point scale); Cost-effectiveness.
Primary and secondary outcomes will be compared at baseline, at 2 and 6 weeks, and at 3, 6, and 12 months after start of treatment, using both univariate and multivariable analyses. Costs for (in)formal healthcare consumption will be determined for both interventions, cost-effectiveness will be expressed as cost per quality of life year (QALY) gained.

RECRUITING COUNTRIES

The Netherlands

Study objective

The main study hypothesis is that by reducing the risk of transsection of the infrapatellar nerve during tibial nailing, post-operative anterior knee pain can be reduced. At one year, we expect less anterior knee pain and better functional status in patients treated with a transverse incision than in patients treated with a longitudinal incision. We also expect fewer complication and less health care use in the transverse incision group. Given these expected differences, the transverse incision is expected to be more cost-effective.

Study design

Baseline, 2 weeks, 6 weeks, 3 months, 6 months, 12 months

Intervention

1) Longitudinal incision and insertion of tibia nail using a transpatellar approach;

2) Transverse incision and insertion of tibia nail using a transpatellar approach

Contacts

Public
Erasmus MC, Trauma Research Unit, dept. of Surgery - Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam

M.H.J. Verhofstad
P.O. Box 2040, 3000 CA Rotterdam
Rotterdam
The Netherlands
+31-10 7031050
Scientific
Erasmus MC, Trauma Research Unit, dept. of Surgery - Mailbox H-822k
's-Gravendijkwal 230, 3015 CE Rotterdam

M.H.J. Verhofstad
P.O. Box 2040, 3000 CA Rotterdam
Rotterdam
The Netherlands
+31-10 7031050

Eligibility criteria

Inclusion criteria

1. Age between 16 and 65 years

2.Unilateral tibial shaft fracture (AO 42 A, B and C)

3. Indication for intramedullary nailing in judgment of the treating surgeon (within 2 weeks after initial trauma)

4. Provided written consent by patient

Exclusion criteria

1. Polytrauma patients, when concurring injury affect treatment and recovery

2. Patients with bilateral tibial fractures

3. Patients with a pathological or recurrent fracture of the tibia

4. Gustilo open fractures grade C or open wound on knee

5. Patients with pre-existing knee pathology (e.g., menisci, cruciate ligament)

6. Patients with pre-existing functional impairment which has influence on rehabilitation (e.g. wheelchair-bound)

7. Patients with rheumatoid arthritis

8. Patients with bone disease resulting in delayed union (except osteoporosis)

9. Insufficient comprehension of Dutch language to adhere to treatment guidelines

10. 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2015
Enrollment:	136
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2015
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
NTR-new	NL4969
NTR-old	NTR5091
Other	NL49144.078.14 : MEC-2014-335

Study results

Summary results
None yet; study is ongoing