Effect of infrapatellar nerve block on chronic anterior knee pain after tibial nailing

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28256

Source
NTR

Brief title
INCOP

Health condition

anterior knee pain
tibial nailing
infrapatellar nerve

pijn aan de voorzijde van de knie
tibiapenplaatsing
nervus infrapatellaris

Sponsors and support

Primary sponsor: St. Elisabeth Hospital, Tilburg, The Netherlands. Gelderse Vallei Hospital, Ede, The Netherlands. Erasmus MC Rotterdam, The Netherlands.
Source(s) of monetary or material Support: St. Elisabeth Hospital, Tilburg, The Netherlands
Gelderse Vallei Hospital, Ede, The Netherlands
Erasmus MC Rotterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

Difference in anterior knee pain (NRS) during kneeling for the most painful activity (measured at baseline) before and after infrapatellar nerve block with lidocaine and sodium chloride at least 6 months after intramedullary nailing

Secondary outcome

Anterior knee pain (NRS) during 8 different activities at least 6 months after tibial nailing.
Anterior knee pain (NRS) during 8 different activities at least 6 months after tibial nailing.
Infrapatellar nerve injury at least 6 months after tibial nailing.

Study description

Background summary

-

Study objective

An infrapatellar nerve block with lidocaine alters anterior knee pain (measured on NRS) in patients 6 months after tibial nailing.

Study design

NRS for anterior kneepain is measured at baseline (at least 6 months after tibial nailing), after first and after second injection.

Intervention

Lidocaine Hydrochloride Injection 2%

Sodium Chloride Injection, USP 0.9%

Contacts

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Eligibility criteria

Inclusion criteria

- Traumatic tibial shaft fracture treated with an intramedullary nail.

- Age between 18 and 65 (during trial).

- Mean NRS 4-6 during at least 3 out of 8 activities or NRS 7 or higher during 1 or more activities.

Exclusion criteria

- Preexistent knee pain or knee problems.

- Contraindication or intolerance for lidocaine.

- Insufficient comprehension of Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2013
Enrollment:	34
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-06-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44044
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4510
NTR-old	NTR4628
CCMO	NL34510.008.11
OMON	NL-OMON44044

Study results