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

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To study the effect of a nerve block of the infrapatellar nerve with local infiltration with lidocaine or saline on chronic anterior knee pain after tibial nailing.Secondairy objectives:- to measure knee pain on a VAS for eight different activities...

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

Summary

ID

NL-OMON44044

Source
ToetsingOnline

Brief title
INCOP

Condition

- Peripheral neuropathies
- Skin and subcutaneous tissue therapeutic procedures

Synonym
anterior knee pain, pain at the anterior aspect of the knee

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Infrapatellar nerve, knee pain, tibial nailing

Outcome measures

Primary outcome

Difference in knee pain measured on the VAS for the most painful activity

before and after injection with lidocaine or saline.

Secondary outcome

Knee pain measured on the VAS for eight different activities more than six

months intramedullary tibial nailing.

Neurological deficits in the dermatome of the infrapatellar nerve

Study description

Background summary

Intramedullary nailing is considered to be the treatment of choice for tibia shaft fractures due to the high union rates, good functional and predictable results, low infection and deformity rates. Nevertheless, postoperative pain and discomfort at the anterior aspect of the knee is one of the most frequent complications after tibial nailing. In a meta-analysis Katsoulis et al report a mean prevalence of anterior knee pain after tibial nailing of 47.4%. In a previous study we found a prevalence of 38% in patients treated in our hospital. It has been attributed to multiple factors such as injury to cartilage, the retropatellar fat pad, the patellar tendon, and nail protrusion. No publication has yet provided conclusive data regarding the etiology of anterior knee pain after tibial nailing and it remains a complex problem. The medullary canal is best approached on the laterale side of medial epicondyl. The incision can be vertical, and placed medially or laterally from the patellar tendon (parapatellar approach). An incision on top of the patellar tendon is also an possibility (transpatellar approach). The incision can also be placed horizontal. There is no 'gold standard' for incision placement for tibial nailing and a vast intersurgical variaty exists. A study comparing the medial parapatellar and the transpatellar incision showed no difference in anterior knee pain. No other studies comparing different incisions are known. Several anatomic structures around the knee are prone to injury during nail

insertion, including the infrapatellar branch of the saphenous nerve. The infrapatellar nerve arises from the saphenous nerve distal to the adductor canal. It then courses laterally to cross the patellar tendon in a transverse way. Cutaneous sensation of the anterior aspect of the knee and the anterior inferior knee capsule is supplied by the infrapatellar nerve. Iatrogenic injury to the nerve will result in predictable sensory loss lateral or downstream to the incision. Additionally, in some individuals neuropathic pain can develop (hypalgesia, dysesthesia or allodynia). This neuropathic component of the pain may even persist in the absence of any peripheral noxious stimuli or ongoing peripheral inflammation. Infrapatellar nerve injury can be caused by surgical trauma. Sensory disturbances have been reported following arthroscopic and open knee surgery in the (medial) knee region. Also neuroma formation and reflex sympathetic dystrophy following infrapatellar nerve injury have been reported. Injury to the infrapatellar nerve is not widely recognized after tibial nailing. Only few authors mention infrapatellar nerve injury after this procedure. In a recent study we showed that injury to infrapatellar nerve was found in 60% of all patients. In patients with chronic anterior knee pain significantly more sensory distubnaces were detected.
The position of the infrapatellar nerve changes when the knee is flected. When a scar has formed after insertion of an intramedullary nail, this sliding mechanism is disrupted. When the infrapatellar nerve runs through the scar tissue and the knee is flected, traction on the nerve may cause neuropatic pain on the anterior aspect of the knee.
A local subcutaneous injection in the scar on the knee with lidocaine will cause only local anaesthesia of the skin that is supplied by the infrapatellar nerve. Sensation of the deeper (intra-articular) structures remains intact. With this intervention an association between chronic anterior knee pain and involvement of the infrapatellar nerve can be detected. This had not yet been studied.

Study objective

To study the effect of a nerve block of the infrapatellar nerve with local infiltration with lidocaine or saline on chronic anterior knee pain after tibial nailing.

Secondairy objectives:
- to measure knee pain on a VAS for eight different activities at least six months after treatment with an intramedullairy nail
- to measure altered sensibility in the dermatome of the infrapatellar nerve after tibial nailing

Study design

A double blind randomised cross over trial with patients treated at St. Elisabeth Hospital Tilburg, Hospital Gelderse Vallei Ede, Erasmus MC Rotterdam

and Radboudumc Nijmegen.

Patients treated with a tibiashaft fractuur treated with an intramedullary nail who have knee pain more than six months with a VAS score > 4 for more than three activities or one activity with a VAS of more than seven. A physical exam will be performed. All eight activities will be perfomed again, under supervision.

Prior to the start of the study, patients were randomly assigned to a treatment sequence, lidocian followed by saline or the other way arounf, by computer-generated random numbers. A co-worker otherwise not participating in the study will open the randomisation envelope and prepare a syringe of 5 ml lidocaine and 5 ml saline. The preparation of the study drug will be done seperate from the area where the nerve block will be performed to ensure a complete blinding procedure. The syringes will subsequently be marked according to the randomization sequence and handed over to the investigator.

After the nerve block patients will again perform all activities listed under supervision. And this is repeated again after nerve block with the second fluid.

Intervention

Nerve block with lidocaine versus placebo medial from the patella (anatomical position of the proximal part of the infrapatellar nerve).

Study burden and risks

In total the visit will be approximately 30 minutes.
Lidocaine is a frequently used local anesthetic. Reactions to lidocaine are characteristic of those associated with other amide-type local anesthetics. A major cause of adverse reactions to this group of drugs is excessive plasma levels, which may be due to overdosage, unintentional intravascular injection, or slow metabolic degradation. The most commonly encountered acute adverse experiences which demand immediate counter-measures are related to the central nervous system and the cardiovascular system. These adverse experiences are generally dose related and due to high plasma levels which may result from overdosage, rapid absorption from the injection site, diminished tolerance, or from unintentional intravascular injection of the local anesthetic solution. Subcutaneous injection with 5 ml of sodiumchloride has negligible risk.

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

Age 18 - 65
Tibiashaft fracture which has been treated with an intramedullary nail more than 6 months earlier

Exclusion criteria

Gustillo III-C open fractures
Pre-operative knee pain
Lost to follow-up
Contraindication for lidocain
Insufficient understanding of the Dutch language to fill in questionaires

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

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

Ethics review

Approved WMO Date:	06-10-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-08-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-07-2014
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-06-2016
Application type:	Amendment

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-07-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28256
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL34510.008.11
OMON	NL-OMON28256

Study results

Date completed:	11-09-2017
Actual enrolment:	34