Analgesic efficacy of saphenous nerve blockade for outpatient knee anterior cruciate ligament surgery

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

Summary

ID

NL-OMON44745

Source
ToetsingOnline

Brief title
Saphenous nerve block in outpatient ACLS

Condition

- Other condition

Synonym
postoperative pain

Health condition

postoperative pain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anterior cruciate ligament, daycare, nerve block, Saphenous

Outcome measures

Primary outcome

Readiness to discharge in hours and according to Post-Anesthetic

Discharge Scoring System (PADSS)

Secondary outcome

Degree of motor blockade, patient satisfaction, pain score (VAS) and overall

benefit of analgesia score (OBAS) for the day of surgery and the first

postoperative day.

- IKDC questionnaire

- KOOS questionnaire

- SF-12

- Sensory blockade extent

- Time to rescue analgesic (morphine postoperatively)

- Total analgesic consumption (telephone interview)

- Time to mobilization (telephone interview)

- Knee function will be done by the Knee Society 6 weeks after surgery

- Incidence of falls or near falls

Study description

Background summary

Anterior cruciate ligament surgery (ACLS) of the knee is a potentially painful procedure, which is increasingly performed on an outpatient basis. The contemporary gold standard for pain treatment is femoral nerve block performed at the inguinal crease, with subsequent numbing of the entire nerve, including motor and sensory function. Motor block may, however, may impair early mobilization and lead to falls. Another possibility is to block only the saphenous nerve, which contains the femoral nerve*s sensory fibers supplying the knee joint. In theory, this will provide the same level of analgesia as a femoral nerve block, but without the accompanying motor weakness.

Study objective

The general aim of this present study is to investigate whether blockade of the saphenous nerve can provide the same degree of analgesia postoperatively for ACLS as a femoral nerve block without resulting motor blockade enhancing shortening of hospital stay en functional outcome.

Study design

Multi-center, prospective, randomized, double-blind clinical trial.

Intervention

Single shot ultrasound-guided mid thigh saphenous nerve blockade for postoperative pain therapy.

Study burden and risks

No additional burden is expected as clinically used routine pain management strategies are compared with each other.

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

Informed consent, age 18-65 years, ASA status I - III, rupture of the anterior cruciate ligament.

Exclusion criteria

Inability to perform written informed consent, contraindication for regional anesthesia, contraindication for general anesthesia, allergy against local anesthetics, BMI > 35, pre-existing diagnosed neuropathy of the operated leg, ingestion of strong opioids, pregnancy or breastfeeding status. History of significant cardiovascular disease (MI, CVA, peripheral vascular disease)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Chirocaine
Generic name:	Levobupivacain
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2013-003684-54-NL
CCMO	NL46184.018.13