

Continuous administration of local anesthetic for pain after amputation above knee

Submission date 14/08/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/06/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Artherosclerosis is a serious condition where the blood vessels (arteries) get blocked by fatty substances. This study is looking at treatment of pain after thigh amputation. The aim is to find out whether a local anesthetic ropivacain given for three days reduces pain after amputation in patients with atherosclerosis.

Who can participate?

Patients who are undergoing above knee amputation as a result of artherosclerosis.

What does the study involve?

The patients are randomly allocated to one of two groups. Each group receives a single dose of local anesthetic or dummy (saline) for three days after the operation. Patients will verbally rate the level of pain. The patients will also receive paracetamol and opioid for the treatment of pain. The patients are contacted 1, 3 and 12 months after the operation.

What are the possible benefits and risks of participating?

The benefit of the study is efficient pain treatment, especially for patients in the future. The risks of the study are minor, as the technique has been used for several years and the local anesthetic is well tolerated.

Where is the study run from?

The study is carried out in eight centers in Finland. The main center is Helsinki University Hospital- Jorvi Hospital, and the other centers are Meilahti Hospital in Helsinki, Turku University Hospital, Oulu University Hospital, Kuopio University Hospital, Tampere University Hospital, Lahti Central Hospital and Jyvaskyla Central Hospital.

When is the study starting and how long is it expected to run for?

It will start on September 2014. The patients will be recruited for two years and will be followed up for 12 months after operation. The last month of recruitment would be September 2016, and the follow up would last until September 2017.

Who is funding the study?

The study is funded by Helsinki University Hospital, Finland.

Who is the main contact?

Dr Hanna von Plato

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2013-003807-20

Study information

Scientific Title

Peripheral local anesthetic infusion for postoperative pain after above knee amputation

Acronym

FinAPain-1

Study objectives

Continuous infusion of local anesthetic will reduce pain after above knee amputation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

HUS Operative Ethics Committee (HUS Operatiivinen eettinen toimikunta); 11/12/2013

Study design

Randomised controlled double-blind study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pain after amputation above knee

Interventions

Continuous peripheral infusion of local anesthetic ropivacaine for 72 hours through two catheters, placed in the sciathic nerve sheath and under the amputation wound. The randomisation was done with computer-generated randomisation list on random.org, in blocks of ten patients. It was done by a person who is not working with the study otherwise. The follow-up is done by a study nurse who contacts the patients by a telephone call on 1, 3 and 12 months after the operation.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ropivacaine

Primary outcome(s)

Pain on the amputated limb 1-5 days after the operation assessed on VRS 0-4.

Key secondary outcome(s)

1. Pain on the amputated limb 1,3 and 12 months after the operation and amputation phantom limb pain 1-5 days after the operation and 1, 3 and 12 months after the operation on VRS 0-4
2. The consumption of opioid 1-5 days after the operation
3. Adverse events

Completion date

01/09/2017

Eligibility

Key inclusion criteria

1. Patients presenting for above knee amputation for atherosclerosis obliterans willing to participate
2. Able to give informed consent
3. Able to assess pain using a verbal rating scale
4. Assessed to be medically stable so that life expectancy exceeds 2 weeks as assessed by recruiting anesthesiologist

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Allergy to amide local anesthetics
2. Operating surgeon unable to insert the catheter as defined in the protocol
3. Planned epidural postoperative pain management

Date of first enrolment

01/09/2014

Date of final enrolment

01/09/2016

Locations**Countries of recruitment**

Finland

Study participating centre

HUS Jorvin sairaala

Espoo

Finland

00029 HUS

Sponsor information**Organisation**

Helsinki University Hospital (Finland)

ROR

<https://ror.org/02e8hzh44>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Helsinki University Hospital (Finland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration