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Continuous administration of local anesthetic for pain after amputation above knee

Submission date
14/08/2014

Recruitment status
No longer recruiting

Registration date
03/09/2014

Overall study status
Completed

Last Edited
19/06/2015

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
2013-003807-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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 Commitee (HUS Operatiivinen eettinen toimikunta); 11/12/2013

Study design
Randomised controlled double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2014

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. Assesssed to be medically stable so that life expectancy exceeds 2 weeks as assessed by recruiting anesthesiologist

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

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
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Sponsor information

Organisation
Helsinki University Hospital (Finland)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Hospital (Finland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration