

Could treatment with prolonged peripheral nerve block reduce phantom limb pain on lower extremity amputation?

Submission date 08/05/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/07/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/01/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Conditions such as diabetes and vascular disease can lead to a reduction of blood supply to one or more limbs, such as a leg. In the worst cases, this can result in gangrene and the affected limb has to be removed (amputated). People who have had a leg amputated often experience what is called phantom pain, where they feel pain from the limb that is no longer there. Phantom pain is a very real phenomenon and can have a damaging effect on a persons well-being and quality of life. It is currently treated using conventional pain killers or by an epidural (EDA - where anaesthetic is injected into the lower back to numb the nerves) but, to date, there is no really effective way to treat the condition. Peripheral nerve blocks (PNB) are often successfully used to relieve pain for people undergoing hip surgery. They work by blocking the pain signals from a nerve to the brain by injecting the area surrounding the nerve with a local anaesthetic. This study will compare the effect of PNB and EDA when used for the treatment of phantom pain.

Who can participate?

Adults aged 65 or older undergoing amputation of one or both legs.

What does the study involve?

Patients are randomly allocated to one of two groups: the intervention group or the control group. The intervention group receives PNB via a thin tube inserted at the back of the knee, whereas the control group receive EDA (usual care). Assessments will focus on phantom pain, phantom sensation and overall wellbeing/quality of life during their stay in the hospital and at 3, 6 and 12 months after surgery.

What are the possible benefits and risks of participating?

We believe that PNB can improve patients well-being and that this pain relief method can provide a secure and durable pain relief. Pain management during and after surgery might shorten the time of immobilization and reduce the risk of other complications.

Where is the study run from?

This study will be conducted in Norrland University Hospital (Sweden).

When is the study starting and how long is it expected to run for?
The study started in May 2014 and will run for 2 years.

Who is funding the study?

1. County Council of Västerbotten (Sweden)
2. Dementia Foundation (Sweden)

Who is the main contact?

Miss Anna Unneby
unneby85@gmail.com

Contact information

Type(s)

Scientific

Contact name

Miss Anna Unneby

Contact details

Umeå University Hospital
Department of Orthopedics
Umeå
Sweden
901 85
-
unneby85@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Could treatment with prolonged peripheral nerve block reduce phantom limb pain on lower extremity amputation? A randomized controlled study

Acronym

AMP-study

Study objectives

Patients who undergo lower leg amputation have less postoperative pain and reduced incidence of phantom pain with long-term treatment with intermittent peripheral nerve block compared with conventional pain management.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of the Faculty of Medicine at Umeå University, 23/01/2014, ref: 2013-413-31M

Study design

Randomized controlled trial

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

Transtibial amputation of one or both legs, phantom limb pain

Interventions

Once the doctor has decided on amputation he/she will contact the research nurse, which in turn will provide written and verbal information about the study to the patient for approval of participation. Then the patient is randomized to a treatment group by drawing lots. A non-transparent envelope is opened containing information about the study and consent forms to be signed. A person who is not included in the study mixes the envelopes with the two treatment options, then placed them in a single junction of the department where the study will be conducted. The person who gives the information to the patient takes the top envelope in the pile.

1. The intervention group receives a peripheral nerve block of the ischiadic nerve by placing a catheter just above the back of the knee using ultrasound adjacent with the ischiadic nerve. This is done in conjunction with the amputation. Postoperatively local anesthetic of Chirocaine 2.5 mg / ml, 20 ml is administered as bolus into the catheter at intervals of 4-6 hours/day. Treatment with peripheral nerve blockade continues until the patient is discharged.
2. The control group receive EDA (epidural) pain management which is currently the usual pain treatment for amputations.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Phantom pain

2. Phantom sensation

Measured from the day of surgery (six times a day, for at least 1 week), from day 7 until discharge 3 times a day and at 3, 6 and 12 months.

Secondary outcome measures

1. Quality of life

2. Subjected well-being [Philadelphia Geriatric Center Morale Scale (PGCMS)]

3. Depression [15-item Geriatric Depression Scale (GDS-15)]

Measured from the day of surgery (six times a day, for at least 1 week), from day 7 until discharge 3 times a day and at 3, 6 and 12 months.

Overall study start date

19/05/2014

Completion date

01/06/2017

Eligibility

Key inclusion criteria

1. Age 65 years or older

2. With a decision from the responsible orthopedic physician that a transtibial amputation of one or both legs is necessary

3. Residents to the county of Norrland University Hospital

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

60

Key exclusion criteria

Younger than age 65

Date of first enrolment

19/05/2014

Date of final enrolment

31/05/2016

Locations

Countries of recruitment

Sweden

Study participating centre

Umeå University Hospital

Umeå

Sweden

901 85

Sponsor information

Organisation

County Council of Västerbotten (Sweden)

Sponsor details

Umeå University Hospital

Umeå

Sweden

901 85

Sponsor type

Government

Website

<http://www.vll.se/default.aspx?id=23095&refid=23096>

ROR

<https://ror.org/04xvhsp09>

Funder(s)

Funder type

Government

Funder Name

County Council of Västerbotten (Sweden)

Funder Name

Dementia Foundation (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration