ISRCTN23704397 https://doi.org/10.1186/ISRCTN23704397

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

Registration date
02/07/2014

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Musculoskeletal Diseases

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