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Prospective, double-blind, randomised trial to assess the efficacy of continuous sciatic /posterior tibial nerve blockade via a neural sheath catheter in lower limb amputees

Submission date
29/05/2007

Recruitment status
No longer recruiting

Registration date
16/07/2007

Overall study status
Completed

Last Edited
13/02/2023

Condition category
Surgery

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

Plain English Summary

Background and study aims
An amputation is the surgical removal of part of the body, such as an arm or leg. In the UK, about 5000 people each year have their leg amputated. Patients usually have a long hospital stay, require long-term rehabilitation and frequently need institutional support on leaving hospital. After surgery, patients may experience severe pain as well as phantom pain and phantom sensations. So-called ‘stump pain’ comes from the wound site itself. Although a good recovery is possible after amputation, pain complicates rehabilitation, making it more difficult to use prosthetic limbs and regain mobility, limiting independence and the ability to work. Chronic pain can also cause depression, sleep deprivation, a reluctance to socialise, and difficulties with everyday activities. Phantom limb pain is particularly difficult to treat, with many sufferers relying on strong painkillers such as morphine. These are not always successful and often cause significant side effects. We are performing a study of a new technique to find out how it affects pain after amputation.

Who can participate?
Patients requiring a below or above knee amputation because of vascular (blood vessel) disease.

What does the study involve?
The new technique involves placing a small tube, called a catheter, directly into the major nerve of the leg (the sciatic nerve) at the time of surgery and infusing a local anaesthetic called levobupivacaine for 4 days. The research team are assessing the effects of this new treatment on pain early after surgery, and the incidence and severity of phantom limb over the following 6 months. The team are also assessing the long-term physical and psychological effects on mood, physical disability and quality of life.

What are the possible benefits and risks of participating?
The researchers believe the new technique that they are investigating has the potential to relieve pain, aid rehabilitation and improve quality of life for people who have had their leg

amputated because of vascular disease. This study will reveal whether their technique does give these benefits. If proved effective, it is possible this technique could also be used in people who are undergoing amputations for other reasons, for example severe traumatic injuries or bone cancer. An effective treatment that relieves pain could make a real difference to people who have had their leg amputated. Coping with pain can be exhausting. Freedom from pain could reduce people's reliance on painkillers and hugely improve their well-being and quality of life. Freedom from pain after surgery could boost patients' chances of making a good recovery and reduce the time spent in hospital. It could help patients use prosthetic limbs more successfully, improve mobility and aid rehabilitation. These factors contribute to providing patients with greater potential for living independently after surgery and of returning to work. In addition, the increased independence and improved body image that come with successful rehabilitation can significantly boost people's self-esteem. There are no specific risks to taking part in the study but patients are attached to a small infusion device for 4 days after surgery.

Where is the study run from?
Leicester Royal Infirmary (UK).

When is the study starting and how long is it expected to run for?
From July 2007 to December 2012.

Who is funding the study?
Action Medical Research (UK).

Who is the main contact?
Dr Jonathan Thompson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2007-000619-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
56481676

Study information

Scientific Title
Prospective, double-blind, randomised trial to assess the efficacy of continuous sciatic/posterior tibial nerve blockade via a neural sheath catheter in lower limb amputees

Study hypothesis
That continuous neural sheath infusion of levobupivacaine after major lower limb amputation will reduce the incidence of late phantom pain/phantom limb sensations and stump pain.

On 16/10/2012 the overall trial end date was changed from 01/01/2010 to 31/12/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee, 13/08/2007, ref: 07/H0405/42

Study design
Randomised placebo-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

Condition
Lower limb amputation

Interventions
Perineural infusion of levobupivacaine 1.25 mg/ml versus placebo for 96 hours after surgery.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levobupivacaine

Primary outcome measure
Current primary outcome measure as of 15/09/2021:
Late stump pain, phantom limb sensations and phantom limb pain up at 6 months after surgery.

Previous primary outcome measure:
Late stump pain, phantom limb sensations and phantom limb pain up to one year after surgery.

Secondary outcome measures
Current secondary outcome measures as of 15/09/2021:
The following will be measured at 6 weeks, 3 months, and 6 months after surgery:
1. Early postoperative pain and morphine requirements
2. Late effects on mood, physical disability and quality of life, measured using the Late Life disability index (quality of life and disability), the 36-item Short Form health survey (SF-36) inventory, (pain and disability) the McGill pain questionnaire (pain) and the University of Leicester Amputee questionnaire (pain and disability)

Previous secondary outcome measures:
1. Early postoperative pain and morphine requirements
2. Late effects on mood, physical disability and quality of life, measured using the Late Life disability index (quality of life and disability), the 36-item Short Form health survey (SF-36) inventory, (pain and disability) the McGill pain questionnaire (pain) and the University of Leicester Amputee questionnaire (pain and disability)

Secondary outcomes will be measured at 6 weeks, 3, 6 and up to 12 months after surgery.

Overall study start date
01/07/2007

Overall study end date
03/10/2012

Eligibility

Participant inclusion criteria
Patients admitted to our vascular unit requiring a below or above knee amputation irrespective of aetiology.

Participant type(s)
Patient

Age group
Not Specified

Sex

Both

Target number of participants
132

Total final enrolment
90

Participant exclusion criteria
Current exclusion criteria as of 24/08/2021:

1. Patients not considered for surgical intervention
2. Patients who are deemed unfit to undergo surgery under general anaesthesia
3. Patients undergoing surgery under regional anaesthesia
4. Patients unable to operate a Patient-Controlled Analgesia (PCA) device or cooperate with evaluation of pain scores e.g. those with confusional states
5. Patients unwilling to consent
6. Allergy to any study medication

Previous exclusion criteria:

1. Patients not considered for surgical intervention
2. Patients who are deemed unfit to undergo surgery under general anaesthesia
3. Patients unable to operate a Patient-Controlled Analgesia (PCA) device or cooperate with evaluation of pain scores e.g. those with confusional states
4. Patients unwilling to consent
5. Allergy to any study medication

Recruitment start date
01/07/2007

Recruitment end date
03/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
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United Kingdom
LE5 4PW
+44 116 258 4199
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Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Research organisation

Funder Name
Association of Anaesthetists of Great Britain and Ireland (UK)

Results and Publications

Publication and dissemination plan
Presentations at scientific meetings and planned publication in a high impact peer reviewed journal.
Data presented in part at BJA Research Forum, December 2019 and published in abstract form in the British Journal of Anaesthesia April 2020

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/04/2020	24/08/2021	No	No
Basic results		24/08/2021	24/08/2021	No	No
Results article		01/04/2020	24/08/2021	Yes	No
Results article		10/02/2023	13/02/2023	Yes	No