

# 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

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| <b>Submission date</b><br>29/05/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>16/07/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>13/02/2023       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### 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  
jt23@le.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jonathan Thompson

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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 objectives**

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**

### **Health condition(s) or problem(s) studied**

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

**Completion date**

03/10/2012

**Eligibility****Key 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

**Key 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

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**Date of first enrolment**

01/07/2007

**Date of final enrolment**

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

c/o Professor David Rowbotham  
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Leicester General Hospital  
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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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a> |         | 01/04/2020   | 24/08/2021 | No             | No              |
| <a href="#">Basic results</a>    |         | 24/08/2021   | 24/08/2021 | No             | No              |
| <a href="#">Results article</a>  |         | 01/04/2020   | 24/08/2021 | Yes            | No              |
| <a href="#">Results article</a>  |         | 10/02/2023   | 13/02/2023 | Yes            | No              |