The role of glutamate in the development of phantom limb pain

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/03/2001		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
01/03/2001		[X] Results		
Last Edited	Condition category	[] Individual participant data		
14/01/2009	Signs and Symptoms			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SP3481

Study information

Scientific Title

A randomised double blind trial of the effect of pre-emptive epidural ketamine on persistent pain after lower limb amputation

Study objectives

To assess the effect of pre-emptively modulating sensory input with epidural ketamine (an NMDA antagonist) on post-amputation pain and sensory processing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Pain

Interventions

All patients will have spinal and epidural anaesthesia with bupivacaine established before amputation and will receive an epidural infusion of bupivacaine for 48 to 72 hours after surgery for post-operative analgesia.

Patients will be randomised to receive either:

- 1. An epidural bolus of ketamine before surgery followed by epidural ketamine infusion for 48 to 72 hours
- 2. A placebo

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Bupivacaine, ketamine

Primary outcome measure

Incidence and severity of post-amputation pain measured at one year.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2001

Completion date

01/01/2007

Eligibility

Key inclusion criteria

- 1. Patients undergoing lower limb amputation for peripheral vascular disease or as a result of complications of diabetes mellitus
- 2. Able to give informed consent and cooperate with pain assessment

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

53

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2001

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

Scotland

Study participating centre
University of Edinburgh Department of Anaesthesia Critical Care and Pain Medicine
Edinburgh
United Kingdom
EH3 9YW

Sponsor information

Organisation

Action Medical Research (UK)

Sponsor details

Vincent House Horsham West Sussex United Kingdom RH12 2DP

Sponsor type

Charity

Website

http://www.action.org.uk/

ROR

https://ror.org/01wcqa315

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

actionmedres, action medical research for children, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2008		Yes	No