

The role of glutamate in the development of phantom limb pain

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

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)

ROR

<https://ror.org/01wcqa315>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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