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The role of glutamate in the development of phantom limb pain

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

United Kingdom

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