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An assessment of the effects of altering blood pressure on cerebral and systemic haemodynamics in patients with acute ischaemic stroke

Submission date 25/08/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 28/10/2005	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 03/03/2016	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

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
N/A

Study information

Scientific Title
An assessment of the effects of altering blood pressure on cerebral and systemic haemodynamics in patients with acute ischaemic stroke

Study objectives
To assess the effects of altering blood pressure on cerebral and systemic haemodynamics in patients with acute ischaemic stroke.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ischaemic Stroke

Interventions
Patients will be randomised to receive intravenous dobutamine or normal saline alone. Dobutamine will be administered at increasing concentrations at 5 minute intervals. Measurements using transcranial doppler, pulse wave analysis and venous blood samples will be taken at baseline and at each 5 minute dose increment.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. The ability of dobutamine to reduce systolic, diastolic and mean arterial BP
2. Safety and tolerability of dobutamine in acute ischaemic stroke.

Secondary outcome measures
90 day modified Rankin, Barthel and mortality.

Overall study start date
01/01/2000

Completion date
01/01/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients of either sex ≥18 years
2. Proven ischaemic stroke on computed tomography (CT)
3. Stroke onset within 96 hours
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Non-ischaemic stroke
2. Unconscious or Scandinavian Neurological Stroke Scale (SNSS) conscious level <4

3. Baseline systolic blood pressure (BP) >180 mmHg or <100 mmHg
4. Baseline diastolic BP >110 mmHg or <60 mmHg
5. Women of childbearing potential/pregnant/lactating

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Stroke Medicine
Nottingham
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Sponsor information

Organisation
University of Nottingham

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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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