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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

Registration date
28/10/2005

Overall study status
Stopped

Last Edited
03/03/2016

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. The ability of dobutamine to reduce systolic, diastolic and mean arterial BP
2. Safety and tolerability of dobutamine in acute ischaemic stroke.

Key secondary outcome(s))
90 day modified Rankin, Barthel and mortality.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Division of Stroke Medicine
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)
The University of Nottingham

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary