

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

<b>Submission date</b> 25/08/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/03/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Philip Bath

### Contact details

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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  $\geq 18$  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

United Kingdom

NG5 1PB

## Sponsor information

**Organisation**

University of Nottingham

**Sponsor details**

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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