ISRCTN89712435 https://doi.org/10.1186/ISRCTN89712435

# Continue Or Stop post-Stroke Antihypertensives Collaborative Study

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|---|---|---|
| **Submission date**<br>28/05/2010 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>28/05/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>27/04/2015 | **Condition category**<br>Circulatory System | |

**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**
2134

# Study information

## Scientific Title
A multicentre, prospective, randomised, open, blinded-endpoint study to assess whether existing antihypertensive therapy should be continued or discontinued within 24-hours of stroke onset and for the subsequent two weeks

## Acronym
COSSACS

## Study objectives
Up to 40% of acute stroke patients on hospital admission are already taking antihypertensive therapy, and most will develop elevated blood pressure levels as an acute complication of the stroke. However, no guidelines exist as to whether antihypertensive therapy should be continued or discontinued following acute stroke. The Continue Or Stop post-Stroke Antihypertensives Collaborative Study (COSSACS) is a multicentre, prospective, randomised, open, blinded-endpoint study to assess whether existing antihypertensive therapy should be continued or discontinued within 24-hours of stroke onset and for the subsequent two weeks.

A study population of 2900 patients with both cerebral infarction and haemorrhage on antihypertensive treatment at hospital admission will be recruited giving the study a 90% power at the 5% significance level to detect a relative reduction of 10% (absolute risk reduction of 6%) in death and dependency between continuation and discontinuation groups at two weeks. Non-dysphagic, hospital-admitted stroke patients will be recruited within 24 hours of stroke onset and also within 24 hours of last dose of pre-existing antihypertensive therapy.

Baseline investigations will include: blood pressure measurement using UA-767 monitor, modified Rankin Score, Barthel Index, National Institutes of Health Stroke Score and Oxfordshire Community Stroke Project Classification. Patients will be centrally randomised by telephone to continue or discontinue pre-existing antihypertensive treatment for a two-week period. Blood pressure, modified Rankin Score, Barthel Index and National Institutes of Health Stroke Score will be repeated at 2 weeks by an observer blinded to the randomised group. Mortality and health-related quality of life outcomes will be centrally recorded at 6 months.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Trent Research Ethics Committee, 22/08/2002, ref: 02/4/051

## Study design
Multicentre randomised interventional treatment trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Acute Care; Disease: Therapy type

## Interventions
Baseline investigations include blood pressure measurement using UA-767 monitor, modified Rankin Score, Barthel Index, National Institutes of Health Stroke Score and Oxfordshire Community Stroke Project Classification.

Patients will be centrally randomised by telephone to continue or discontinue pre-existing antihypertensive treatment for a two-week period.

Blood pressure, modified Rankin Score, Barthel Index and National Institutes of Health Stroke Score will be repeated at 2 weeks by an observer blinded to the randomised group. Mortality and health-related quality of life outcomes will be centrally recorded at 6 months.

Follow-up length: 6 months
Study entry: single randomisation only

## Intervention Type
Other

## Phase
Phase III

## Primary outcome measure
Death or dependancy (modified Rankin Score greater than 3) at 2 weeks post-randomisation

## Secondary outcome measures
Early outcomes, measured at 2 weeks and 6 months:
1. Neurological deterioration
2. Functional status
3. Blood pressure changes from admission and discharge

Late outcomes:
4. Death and dependency
5. Fatal and non-fatal stroke recurrence
6. Functional status
7. Health-related quality of life

## Overall study start date
01/01/2001

## Completion date
31/03/2009

# Eligibility

### Key inclusion criteria
1. Aged greater than or equal to 18 years, either sex
2. Stroke onset greater than or equal to 48 hours (for suspected stroke, onset time is last time patient was asymptomatic)
3. Clinical diagnosis of suspected stroke by neuroimaging before or after study entry to exclude non-stroke diagnoses and define stroke type
4. Currently receiving antihypertensive treatment and within 48 hours or last dose
5. Informed patient consent or relative/carer consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned sample size: 3000; UK sample size: 3000

### Key exclusion criteria
1. Hypertensive encephalopathy
2. Hypertension greater than 200/120 mmHg in association with intracerebral haemorrhage
3. Co-existing cardiac or vascular emergency
4. Contraindications to stopping antihypertensive therapy
5. Impaired conscious level
6. Dysphagia
7. Premorbid dependence
8. Co-existing life-threatening condition with life expectancy less than 6 months
9. Females of child-bearing potential
10. Non-stroke diagnoses

### Date of first enrolment
01/01/2001

### Date of final enrolment
31/03/2009

# Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**University of Leicester**
Leicester
United Kingdom
LE2 7LX

# Sponsor information

**Organisation**
University Hospitals of Leicester NHS Trust (UK)

**Sponsor details**
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.uhl-tr.nhs.uk/

**ROR**
https://ror.org/02fha3693

# Funder(s)

**Funder type**
Charity

**Funder Name**
Health Foundation (UK)

# 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/02/2005 | | Yes | No |
| Results article | results | 01/08/2010 | | Yes | No |
| Results article | results | 01/06/2015 | | Yes | No |