# Continue Or Stop post-Stroke **Antihypertensives Collaborative Study**

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

### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

#### Type(s)

Scientific

#### Contact name

Prof Thompson G Robinson

#### Contact details

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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