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Continue Or Stop post-Stroke Antihypertensives Collaborative Study

Submission date
28/05/2010

Recruitment status
No longer recruiting

Registration date
28/05/2010

Overall study status
Completed

Last Edited
27/04/2015

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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

Study type(s)
Treatment

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(s)
Death or dependancy (modified Rankin Score greater than 3) at 2 weeks post-randomisation

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Health Foundation (UK)

Results and Publications

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