Acute Candesartan Cilexetil Outcomes Stroke Trial

Recruitment status	 Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Last EditedCondition category26/09/2019Circulatory System	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

NCT00108706

Secondary identifying numbers

0002

Study information

Scientific Title

Acute Candesartan Cilexetil Outcomes Stroke Trial

Acronym

ACCOST

Study objectives

To determine the clinical effectiveness of the ARB Candesartan Cilexetil in improving outcome following acute stroke when administered within the first 72 hours.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double blind placebo controlled 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

Acute stroke

Interventions

Patients will be randomised to receive either Candesartan (intervention group) or placebo. After four weeks of double blind treatment, patients will have their clinic blood pressure treated to target level (<140/85) with either a Candesartan based regimen (active group) or an Angiotensin Concerting Enzyme Inhibitor (ACEI) based regimen 'usual best care' (control group). Patients will be followed to 12 weeks post stroke.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

To determine the safety of the proposed methodology and how many primary end points (combined or single) may be configured for evaluation in a large randomised controlled trial.

Secondary outcome measures

The early effects of Candesartan upon blood pressure following stroke when used within an explicit evidence based protocol.

Overall study start date

01/12/2004

Completion date

01/06/2006

Eligibility

Key inclusion criteria

- 1. Clinical diagnosis of acute ischaemic stroke within 72 hours of symptom onset (proven on CT imaging).
- 2. Medically stable with no evidence of acute infection and not receiving antibiotic therapy.
- 3. Neurologically stable with no progression on NIHSS.
- 4. Able to swallow safely and able to tolerate unthickened oral fluids without risk of aspiration.
- 5. Mean blood pressure in the unaffected arm >120/70 from three readings taken within one hour at twenty minute intervals using a calibrated Omron M5-1 BP monitor.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

50

Kev exclusion criteria

- 1. Previous severe disability (Modified Rankin Score greater to or equal to 3).
- 2. Nursing home resident.
- 3. Previous history of congestive cardiad failure requiring treatment with an ACE inhibitor or Angiotensin Receptor Blocker (ARB).
- 4. Renal impairment (defined serum creatinine >200 umol/l).
- 5. Women of child bearing potential.
- 6. Minors aged less than 18.
- 7. History of evidence of dementia without capacity for consent.

Date of first enrolment

01/12/2004

Date of final enrolment

01/06/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation

City Hospitals Sunderland NHS Foundation Trust (UK)

Sponsor details

Research & Development Kayll Road Sunderland England United Kingdom SR6 OLA

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Industry

Funder Name

Takeda UK Ltd. (UK) - Unrestricted educational grant

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration