

Acute Candesartan Cilexetil Outcomes Stroke Trial

Submission date 07/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 26/09/2019	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00108706

Protocol serial number
0002

Study information

Scientific Title

Acute Candesartan Cilxetil Outcomes Stroke Trial

Acronym

ACCOST

Study objectives

To determine the clinical effectiveness of the ARB Candesartan Cilxetil 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

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

Study type(s)

Treatment

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 Converting 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Previous severe disability (Modified Rankin Score greater to or equal to 3).
2. Nursing home resident.
3. Previous history of congestive cardiac 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

United Kingdom

England

Study participating centre

City Hospitals Sunderland NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation

City Hospitals Sunderland NHS Foundation Trust (UK)

Funder(s)

Funder type

Industry

Funder Name

Takeda UK Ltd. (UK) - Unrestricted educational grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration