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Acute Candesartan Cilexetil Outcomes Stroke Trial

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

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 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 0LA

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 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