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# Acute Candesartan Cilexetil Outcomes Stroke Trial

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

**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 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

## 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 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(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 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
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