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Scandinavian Candesartan Acute Stroke Trial

Submission date 08/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/11/2006	**Overall study status** Completed	
Last Edited 06/04/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.scast.no

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00120003

Secondary identifying numbers

Version/Date 050708

Study information

Scientific Title

Acronym
SCAST

Study objectives
The Angiotensin Type 1 (AT1) receptor blockade with candesartan in acute stroke will:
1. Reduce the risk of death or major disability at six months by a 6% absolute risk reduction, relative to placebo
2. Reduce the risk of the combined event of 'vascular' death, myocardial infarction, or stroke during the first six months by a 25% relative risk reduction, relative to placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committees of :
1. Norway: 21st December 2004 (ref: 700-04250)
2. Sweden: 9th March 2005 (ref: 2005:040)
3. Denmark: 14th March 2005 (ref: 02258454)
4. Belgium: 23rd November 2005 (ref: ML3286)

Study design
Multicentre, randomised- and placebo-controlled, double blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute stroke

Interventions
Candesartan or matching placebo for seven days (4 - 16 mg)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Candesartan

Primary outcome measure
1. Death or major disability (defined by the modified Rankin Scale) at six months
2. The composite event vascular death, myocardial infarction, or stroke during the first six months

Secondary outcome measures
Clinical outcomes:
1. Scandinavian Stroke Scale score at seven days
2. Modified Rankin Scale score at seven days and one, three and six months
3. Barthel Index score at six months
4. EuroQol instrument score at six months
5. Mini-Mental State score at six months

Adverse events:
During the six months follow-up period:
1. Death (all-cause death and vascular death)
2. Recurrent stroke (ischaemic, haemorrhagic, or unspecified)
3. Myocardial infarction
4. Combination of the above events
5. Other adverse events: neurological deterioration, symptomatic hypotension, renal failure, symptomatic venous thromboembolism

Health-economic measures:
Costs related to:
1. Length of hospital stay
2. Discharge disposition
3. Re-hospitalisations during the first six months

Overall study start date
01/06/2005

Completion date
01/06/2008

Eligibility

Key inclusion criteria
1. Clinical stroke syndrome with limb paresis, not likely to represent a transient ischaemic attack or non-stroke pathology (e.g. cerebral tumour)
2. Systolic blood pressure more than or equal to 140 mmHg
3. Trial treatment possible within 30 hours of symptom onset. If time of onset is not known, use

the time when the patient was last known to be well
4. Consent (subsidiary, assent from legal acceptable representative, or waiver of consent)
5. Aged over 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2,500

Key exclusion criteria
1. Markedly reduced consciousness (i.e. Scandinavian Stroke Scale consciousness score less than or equal to two)
2. Patient already receiving AT1 receptor blocker
3. Contraindication to treatment with AT1 receptor blocker, e.g.:
3.1. Known renal failure (women: creatinine more than or equal to 150 µmol/L; men: more than or equal to 180 µmol/L)
3.2. Previously diagnosed bilateral renal artery stenosis
3.3. Previously diagnosed high-grade aortic stenosis
3.4. Previously diagnosed seriously impaired liver function and/or cholestasis
3.5. Known intolerance to candesartan or other tablet ingredients
4. Clear indication, in the clinicians view, for start of treatment with AT1 receptor blocker during the treatment period (e.g. chronic heart failure grade III to IV, in the presence of intolerance to Angiotensin Converting Enzyme [ACE] inhibitors)
5. Clear indication, in the clinicians view, for anti-hypertensive therapy during the acute phase of stroke (i.e. concurrent hypertensive encephalopathy or aortic dissection, or other situations)
6. Other serious or life-threatening disease before the stroke:
6.1. Patient severely mentally or physically disabled (e.g. Mini Mental Status score less than 20, or modified Rankin Scale score more than or equal to four)
6.2. Life expectancy less than 12 months
7. Patient unavailable for follow-up (e.g. no fixed address)
8. Pregnant or breast-feeding woman

Date of first enrolment
01/06/2005

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
Belgium

Denmark

Norway

Sweden

Study participating centre
Department of Internal Medicine
Oslo
Norway
NO-0407

Sponsor information

Organisation
Ullevaal University Hospital (Norway)

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Sponsor type
Hospital/treatment centre

Website
http://www.ulleval.no

ROR
https://ror.org/00j9c2840

Funder(s)

Funder type
Government

Funder Name
Eastern Norway Regional Health Authority (Norway)

Funder Name
Ullevaal University Hospital (Norway)

Funder Name
AstraZeneca Ltd

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/02/2011		Yes	No