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Candesartan in renal artery stenosis (CARLAS)

Submission date 09/10/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/12/2007	**Overall study status** Completed	
Last Edited 18/12/2007	**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

Protocol serial number
S 131-03

Study information

Scientific Title

Acronym
CARLAS

Study objectives
Despite beneficial effects on blood pressure with endovascular treatment, the prognosis remains ominous in patients with renal artery stenosis because of increased cardiovascular mortality. In patients with atherosclerotic renal artery stenosis, the mortality is increased six-fold compared to an age-matched population. It is reasonable to speculate that the high cardiovascular mortality in patients with renal artery stenosis could partly be explained by increased inflammatory activity caused by activation of the renin-angiotensin system. We believe that Percutaneous Transluminal Renal Angioplasty (PTRA) followed by angiotensin receptor blockade may improve this disease state.

The angiotensin receptor blocker candesartan given to patients with renovascular hypertension post-PTRA, will improve long-term renal function (3 years) and decrease the risk of restenosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethical Committees of the Universities of Göteborg and Lund on the 14th of April 2003.

Study design
A two-center randomized controlled open study.

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Renal artery stenosis

Interventions
This study is carried out at two centers in Sweden (Göteborg and Malmö).

Four weeks after renal angioplasty, all subjects will be randomized to anti-hypertensive treatment with either candesartan (oral) (intervention group) or conventional anti-hypertensive treatment (control group). The choice of drug used for the treatment of each participant in the control group will depend on his/her condition. The choices are betablockers, calcium antagonists, diuretics and alphablockers.

The maximum daily doses: 200 mg for metoprolol (betablocker), 20 mg for felodipine (calcium antagonist), as much as needed for furosemide (diuretic), 8 mg for doxazosin (alphablocker). Candesartan was titrated up to a dose of 16 mg once daily.

Duration of intervention: three years

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome(s)
Renal function measured by EDTA-clearance and frequency of restenosis 3 years after PTRA.

Key secondary outcome(s))
Cardiovascular events 3 years after PTRA.

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Blood pressure above 140 mmHg/90 mmHg
2. Confirmation of renal artery stenosis by either duplex ultrasonography, CT-angiography or MR-angiography

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Renal size <7.5 cm at the stenotic side
2. Age >80 years
3. Pregnancy or nursing mother
4. Terminal renal failure (Glomerular Filtration Rate [GFR] <15 ml/min)
5. Treatment with Angiotensin-Converting Enzyme (ACE) inhibitors or angiotensin receptor blockers
6. Renovascular hypertension of other etiology than atherosclerosis or Flow-Mediated Dilation (FMD)
7. Chronic glomerular disease with urinary albumin excretion (in mg/24h) (tU-alb) >1g/day
8. Diabetic nephropathy with tU-alb >0.3 g/day
9. Contraindication for renal angiography/PTRA (eg. serious contrast allergy)
10. Other forms of secondary hypertension
11. Serious malignant disease
12. Treatment with immune-modulating medications eg. cyclosporin and oral steroids

Date of first enrolment

15/04/2003

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Nephrology
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Sponsor information

Organisation
AstraZeneca (Sweden)

ROR
https://ror.org/04wwrrg31

Funder(s)

Funder type
Industry

Funder Name
The Ernhold Lundström Foundation (Sweden)

Funder Name
Research Funds at Malm General (University) Hospital (Malm Allmnna Sjukhus - MAS) (Sweden)

Funder Name
The Albert Påhlsson Foundation (Sweden)

Funder Name
The Hulda Ahlmroth Foundation (Sweden)

Funder Name
The Göteborg Medical Society (Sweden)

Funder Name
The Swedish Medical Society

Funder Name
The Swedish Association for Kidney Patients

Funder Name
AstraZeneca, Mölndal (Sweden)

Funder Name
The Swedish state under the LUA/ALF agreement

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration