Comparison between beta-adrenergic blockers and angiotensin II receptor antagonists for the treatment of late hypertension in patients with repaired aortic coarctation

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To investigate whether treatment with candesartan (ARB) reduce 24-hours systolic BP and aortic stiffness more effectively than treatment with metoprolol (beta-blocker) in patients with repaired CoA and late hypertension.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON30486

Source
ToetsingOnline

Brief title
Treatment of late hypertension in aortic coarctation

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Vascular hypertensive disorders

Synonym
aortic coarctation, hypertension

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angiotensin II receptor blockers, aortic coarctation, beta-blockers, hypertension

Outcome measures

Primary outcome

The primary study parameter will be the reduction in 24-hours systolic blood pressure after 8 weeks of active treatment.

Secondary outcome

The secondary study parameter will be the reduction in aortic stiffness as assessed by aortic pulse wave velocity. Tertiary study parameters will be changes in plasma values of NT-proBNP, rennin, aldosteron, noradrenalin, adrenalin, and endothelin-1.

Study description

Background summary

Systemic hypertension is one of the major long-term problems following repair of coarctation of the aorta (CoA). Research on specific treatment of hypertension in these patients is not available and current treatment strategies are based on hypertension treatment in other patient groups. In our institution, most CoA patients with late hypertension receive different antihypertensive agents (i.e. beta-blockers, ACE-inhibitors, angiotensin receptor blockers (ARB), diuretics).

Study objective

To investigate whether treatment with candesartan (ARB) reduce 24-hours

systolic BP and aortic stiffness more effectively than treatment with metoprolol (beta-blocker) in patients with repaired CoA and late hypertension.

Study design

Single center, open, randomised, cross-over study during a 1-year period.

Intervention

After a washout period of 3 weeks for patients previously on antihypertensive agents, patients will be randomised to treatment with candesartan first (Group A) or metoprolol first (Group B) for 8 weeks. After a washout period of 3 weeks, patient will receive the other active treatment for another 8 weeks. Candesartan 8 mg and metoprolol 100 mg will be used, respectively.

Study burden and risks

The study period for the individual patient is approximately 6 months. During this period, the subject will have 24-hours ambulatory BP monitoring on 4 different occasions. Furthermore, laboratory testing and ultrasound examination will take place (4 times). Metoprolol and candesartan are widely prescribed antihypertensive agents with low adverse events rates, and are currently also used in CoA patients. The current study may provide valuable information regarding the beneficial role of ARBs in CoA patients.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosis of aortic coarctation (EPCC code 09.29.01)
- Previous repair of aortic coarctation
- Age 18-80 years
- Current use of anti-hypertensive medication (<3 different drugs), or untreated hypertension, defined as systolic >=140 mmHg or diastolic >=90 mmHg

Exclusion criteria

- Known oversensitivity for candesartan or metoprolol
- Severe liver insufficiency (ASAT or ALAT >3ULN)
- Current use of >=3 anti-hypertensive drugs
- Pregnancy or wish to become pregnant
- General contraindications for use of candesartan
- General contraindications for use of metoprolol (i.e. bradycardia, sick sinus syndrome etc)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2007
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Atacand
Generic name:	Candesartan
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Selokeen
Generic name:	Metoprolol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-02-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-006861-18-NL
CCMO	NL15692.078.06