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Angiotensin II Receptor Blockers in patients with systemic right ventricles

Submission date	Recruitment status	[_] Prospectively registered
28/09/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2013	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ccmo.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CVAL489ANL09

Study information

Scientific Title

Acronym
ARBs and systemic right ventricles.

Study objectives
Treatment with an angiotensin II receptor blocker (valsartan) stabilises or improves the functional performance of the systemic right ventricle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Transposition of the great arteries, systemic right ventricle

Interventions
One group receives twice daily a 160 mg tablet of valsartan and the other group receives twice daily a placebo tablet.

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome measure
The change in right ventricular ejection fraction, determined by Cardiovascular Magnetic Resonance (CMR) (valsartan versus placebo). In patients who are not eligible for CMR the right ventricular ejection fraction is determined by echocardiography.

Secondary outcome measures
1. Changes congestive heart failure?
2. Changes the prevalence of supra-ventricular arrhythmias?
3. Changes in right ventricular function, determined by body surface mapping?
4. Changes the right ventricular volume?
5. Changes the peak oxygen consumption during exercise?
6. Changes the serum neurohormone levels?
7. Changes the quality of life and sport activity?
8. Changes the cardiac output and microcirculation?
9. Changes the number of deaths?

Overall study start date
01/09/2006

Completion date
01/01/2010

Eligibility

Key inclusion criteria
All adult patients with a systemic right ventricle due to a congenitally or surgically corrected transposition of the great arteries.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
128

Key exclusion criteria
1. Incapable of giving informed consen
2. Hypersensitivity to valsartan or any of its help substances
3. Known bilateral renal artery stenosis
4. Current symptomatic hypotension

5. Myocardial infarction, stroke or open-heart surgery in the previous four weeks
6. Previous heart transplant, or expected heart transplant within the next six months
7. Plasma creatinine level more than 250 µmol/L
8. Plasma potassium level more than 5.5 mmol/L
9. Pregnant or nursing women (a pregnancy test is offered to every female patient within the fertile age)
10. Desire to have children within the study period
11. Current treatment of hypertension with Angiotensin II receptor blockers or Angiotensin Converting Enzyme (ACE) inhibitors

Date of first enrolment
01/09/2006

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma B.V. (The Netherlands)

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?
Protocol article	protocol	01/11/2010		Yes	No
Results article	results	22/01/2013		Yes	No