

Angiotensin II Receptor Blockers in patients with systemic right ventricles

Submission date 28/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 28/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/05/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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?

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Incapable of giving informed consent
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 $\mu\text{mol/L}$
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)

ROR
<https://ror.org/03t4gr691>

Funder(s)

Funder type
Industry

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

Results and Publications

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	22/01/2013		Yes	No
Protocol article	protocol	01/11/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes