Angiotensin II Receptor Blockers in patients with systemic right ventricles

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

Contact name

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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

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

Kev 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? |
|-------------------------|----------|--------------|------------|----------------|-----------------|
| <u>Protocol article</u> | protocol | 01/11/2010 | | Yes | No |
| Results article | results | 22/01/2013 | | Yes | No |