Angiotensin II receptor blockers in patients with systemic right ventricles.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21444

Source
NTR

Brief title
ARBs and systemic right ventricles.

Health condition

Systemic right ventricle due to a congenitally or surgically corrected transposition of the great arteries.

Sponsors and support

Primary sponsor: Academic Medical Centre
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
Source(s) of monetary or material Support: Funded by Novartis Pharma B.V.

Intervention

Outcome measures

Primary outcome

The change in right ventricular ejection fraction, determined by Cardiovascular Magnetic

Resonance (CMR) (valsartan vs. placebo). In patients who are not eligible for CMR the right ventricular ejection fraction is determined by echocardiography.

Secondary outcome

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?

Study description

Background summary

Nowadays, there are over 25,000 adult patients with a systemic right ventricle due to a congenitally or surgically corrected transposition of the great arteries. This means that the right ventricle is responsible for maintaining the circulation of the body. These patients have an increased risk of various cardiac disorders, causing deterioration of their clinical condition and contributing to their premature deaths. The latter is mainly caused by progressive heart failure of the systemic right ventricle, which is present in 90% of all adults with a systemic right ventricle. It has been demonstrated that the degree of right ventricular dysfunction correlates with myocardial fibrosis and right ventricular hypertrophy.
Angiotensin II receptor blockers (ARB) have a proven beneficial effect in patients with left ventricular dysfunction. They protect the myocardium by decreasing myocardial fibrosis and ventricular hypertrophy. Until now, these findings have not been proven to be applicable to patients with a systemic right ventricle. Only one study was performed on the patient, finding no benefits on the exercise capacity and the serum neurohormone levels in these patients. However, from this study it is difficult to draw definite conclusions on the role of ARB’s in patients with a systemic right ventricle, as the study was inadequately powered (only 29 patients), had a short follow-up period (only 15 weeks) and had inappropriate and inaccurate endpoints3. Therefore, a large scale, long term trial, with clear and accurate endpoints is essential to provide an optimal and evidence-based long term treatment and a better future for these patients.

Study objective

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

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 > 250 µmol/L;
8. Plasma potassium level > 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 ACE inhibitors.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-07-2006
Application type:	First submission

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
NTR-new	NL716
NTR-old	NTR726
Other	: CVAL489ANL09
ISRCTN	ISRCTN52352170

Study results

Summary results
N/A