Angiotensin II receptor blockers in patients with systemic right ventricles.

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To study whether ARB's (valsartan) improves functional (contractile, electrophysiologic) performance of the right ventricle in adult patients with a systemic right ventricle.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON30035

Source
ToetsingOnline

Brief title
ARB in TGA

Condition

- Congenital cardiac disorders

Synonym
Transposition of the great arteries; congenitally corrected transposition of the great arteries

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Farmaceutische industrie,Novartis

Intervention

Keyword: angiotensin II receptor blocker, cardiovascular magnetic resonance, right

ventricle, transposition of the great arteries

Outcome measures

Primary outcome

Change in right ventricular function ejection fraction, determined by

Cardiovascular Magnetic Resonance (CMR) (valsartan vs. placebo).

Secondary outcome

changes congestive heart failure?

changes the prevalence of supra-ventricular arrhythmias?

changes in right ventricular function, determined by body surface mapping?

changes the right ventricular volume?

changes the peak oxygen consumption during exercise?

changes the serum neurohormone levels?

changes the quality of life and sport activity?

changes the cardiac output and microcirculation?

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 in the Western World. This means that in these patients 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 the right ventricular dysfunction correlates with the extent of myocardial fibrosis and

right ventricular hypertrophy.
Angiotensin II receptor blockers (ARB*s) 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 that found 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 endpoints. 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.

The results of the proposed study helps to guide the long-term treatment of this unique patient population by accurately determining the impact of ARBs on the systemic right ventricular function. To prevent progressive dysfunction of the systemic right ventricle, improve the quality of life and postpone the premature deaths of these young patients would be major triumphs in modern medicine.

Study objective

To study whether ARB's (valsartan) improves functional (contractile, electrophysiologic) performance of the right ventricle in adult patients with a systemic right ventricle.

Study design

Randomized, double-blind, prospective, multi-centre trial, follow-up 3 years.

Intervention

Valsartan start dose 160mg 1dd1, will be increased to 160 mg 2dd1 with a two week interval.

Study burden and risks

The investigations that will be performed on the patients are all non-invasive, except for the blood tests, and free of risk. The burden for the patients will mainly be the time consumed by the various investigations.
The number of side effects from valsartan are low. The most common side effect is dizziness due to a decrease of blood preasure (> 1:100 and < 1:10 patients). Serious of fatal side effects have not been described.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Systemic right ventricle
Adult (18 years or older)

Exclusion criteria

Incapable of giving informed consent
Hypersensitivity to valsartan or any of its help substances
Known bilateral renal artery stenosis
Current symptomatic hypotension
Myocardial infarction, stroke or open-heart surgery in the previous four weeks
Previous heart transplant, or expected heart transplant within the next six months

Plasma creatinine level > 250 µmol/L
Plasma potassium level > 5,5 mmol/L
Pregnancy or breast feeding
Desire to have children within the study period

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	128
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Diovan
Generic name:	Valsartan
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	02-08-2006
Application type:	First submission

Review commission: METC Amsterdam UMC

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	EUCTR2006-002262-19-NL
CCMO	NL11977.018.06