Angiotensin II receptor blockers in patients with systemic right ventricles.

Gepubliceerd: 03-07-2006 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21444

Bron
Nationaal Trial Register

Verkorte titel
ARBs and systemic right ventricles.

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Centre
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
Overige ondersteuning: Funded by Novartis Pharma B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-07-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL716
NTR-old	NTR726
Ander register	: CVAL489ANL09
ISRCTN	ISRCTN52352170

Resultaten

Samenvatting resultaten
N/A