The role of Bosentan in fontan patients: improvement of aerobic capacity.

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In adult Fontan patients, treatment with bosentan, an endothelin receptor antaganost (ERA) lowers the pulmonary vascular resistance, which may result in improvement of the cardiopulmonary circulation and functional capacity...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24216

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

aerobic capacity (peak V'O2)
quality of life
prevalence of arrhythmias
prevalence of protein losing enteropathy

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: Actelion Pharmaceuticals provide study medication

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to determine changes in aerobic capacity (peak V’O2) in adult patients with a Fontan circulation before and after treatment with the bosentan and compared to non-treated patients.

Toelichting onderzoek

Achtergrond van het onderzoek

The Fontan procedure is a palliative surgical procedure used in patients with complex congenital heart defects. It involves diverting the venous blood from the right atrium to the pulmonary arteries without passing through the right ventricle. A low pulmonary vascular resistance (PVR) is crucial to preserve the Fontan circulation. Plasma endothelin-1 level, a vasoconstrictor which increases pulmonary vascular resistance, is elevated in patients with Fontan circulation. Treatment with bosentan, an endothelin receptor antagonist (ERA) lowers the pulmonary vascular resistance, which may result in improvement of the cardiopulmonary circulation.

Doel van het onderzoek

In adult Fontan patients, treatment with bosentan, an endothelin receptor antaganost (ERA) lowers the pulmonary vascular resistance, which may result in improvement of the cardiopulmonary circulation and functional capacity.

Onderzoeksopzet

baseline, 3 months, and after 6 months of bosentan treatment.

During bosentan treatment regularly laboratory testing will be performed

Onderzoeksproduct en/of interventie

One group receives a 125 mg tablet of Bosentan twice daily for 6 months. The other group does not receive study medication for the first 3 months, followed by treatment with study medication for 6 months.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All adult Fontan patients are potentially eligible for this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients are not eligible for this study if the following inclusion criteria apply:

1. Systemic arterial pressure < 85 mmHg

2. Incapable of giving informed consent

3. Hypersensitivity to bosentan or any of its help substances

4. Current treatment with bosentan or treatment for pulmonary arterial hypertension

5. Moderate to severe liver disease: Child-Pugh class B or C

6. Raised plasma transaminases level > three times limiting value

7. Simultaneous use of cyclosporine A
8. Desire to have children within the study period or women who do not use reliable contraceptive methods

9. Pregnant or nursing women

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1487
NTR-old	NTR1557
Ander register	: 03602
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A