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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24216

Source
NTR

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Actelion Pharmaceuticals provide study medication

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To determine the effect of the following parameters.

- changes in six-minute-walk-distance

- changes in quality of life score

- changes in prevalence of arrhythmias

- changes in congestive heart failure
(hospital admission, use of medication for congestive heartfailure)

- changes in prevalence of protein losing enteropathy

- changes in serum neurohormone level (NT-pro BNP, endothelin-1, albumin)

- changes in cardiac output

- changes in arterial oxygen saturation

- changes in number of deaths

Study description

Background summary

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.

Study objective

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.

Study design

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

During bosentan treatment regularly laboratory testing will be performed

Intervention

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.

Contacts

Public
Academic Medical Centre (AMC)
Department of cardiology
Room F3 – 115
B.J.M. Mulder
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666051
Scientific
Academic Medical Centre (AMC)
Department of cardiology
Room F3 – 115
B.J.M. Mulder
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666051

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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

Study results

Summary results
N/A