ACE inhibition in Fontan patients: its effect on body fluid regulation.

Gepubliceerd: 20-07-2017 Laatst bijgewerkt: 19-03-2025

ACE-inhibition will exaggerate the responsiveness to central blood volume depletion, will increase the responsiveness to fluid challenges, will result in a decrease aortic pulse wave velocity, a better cardiac autonomic profile and an increase in...

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

Samenvatting

ID

NL-OMON27721

Bron
NTR

Verkorte titel
SAFE

Aandoening

Fontan patients/palliation/circulation/surgery

Single ventricle, univentricular heart

ACE-inhibition, Enalapril

Ondersteuning

Primaire sponsor: Leiden University Medical Centre (LUMC)
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Cardiopulmonary exercise stress test: VO2peak.
- Cardiac autonomic nervous activity: heart rate variability and pre-ejection period.
- Outcome of passive leg raising and head up tilt table testing: cardiac output and cardiac autonomic tone.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: There is no consensus on the use of ACE inhibition in Fontan patients without ventricular dysfunction. Multiple centres prescribe enalapril on a routine base for patients with a Fontan circulation and a preserved ventricular function, while other centres have considerable doubt about its effectiveness. Too little research has been done to the effectiveness of ACE inhibition in Fontan patients. There are as yet no studies available that investigate the effect of ACE inhibition on various cardiovascular parameters in patients with a Fontan circulation. By studying the effect of ACE inhibition on cardiovascular parameters as systolic and diastolic ventricular function, cardiac output, and the sensitivity of the cardiovascular system to fluid changes, the basic effects of ACE inhibition on the cardiovascular system of Fontan patients will become more clear. This will result in a more appropriate selection of patients that will profit of the use of ACE inhibitors.

Main objective: To treat Fontan patients for 3 months with the ACE inhibitor enalapril and compare a set of cardiovascular measurements before and after treatment in order to study its effect on the cardiovascular system and the effect of a reversible fluid challenge and depletion in Fontan patients, and to correlate all these results with the results of a symptom limited maximal exercise test.
Study design: This study consists of a longitudinal intervention study and a cross-sectional study.

Study population: 55 patients with a univentricular heart after palliation with the Fontan circulation will be included from an age of 8 until 18 years old. Patients who already use enalapril will be excluded. A number of fifty healthy age and gender matched subjects will serve as controls.

Intervention (if applicable): To all Fontan patients enalapril will be given twice daily at a dose of 0,5 mg/kg/day with a maximum of 20 mg per day. All Fontan patients will undergo all the investigations before and after treatment and healthy controls will undergo all the investigations once.

Main study parameters/endpoints:

- Cardiopulmonary exercise stress test: VO2peak.

- Cardiac autonomic nervous activity: heart rate variability and pre-ejection period.

- Outcome of passive leg raising and head up tilt table testing: cardiac output and cardiac autonomic tone.

Doel van het onderzoek

ACE-inhibition will exaggerate the responsiveness to central blood volume depletion, will increase the responsiveness to fluid challenges, will result in a decrease aortic pulse wave velocity, a better cardiac autonomic profile and an increase in cardiopulmonary stress testing.

Onderzoeksopzet

All Fontan patients will be undergo all the investigations before and after treatment, with a treatment duration of 3 months, and healthy controls will undergo all the investigations once.

Onderzoeksproduct en/of interventie

This study consists of a longitudinal intervention study and a cross-sectional study

In the present study we will compare several cardiovascular measurements before and after treatment of enalapril, in patients with a univentricular heart after palliation with the Fontan circulation. Patients will start with treatment of enalapril after all cardiovascular measurements at baseline have been performed. After a 3-month period of treatment with enalapril (0,5mg/kg/day with a maximum of 20mg per day), all cardiovascular measurements will be repeated.

Healthy age and gender matched subjects will serve as controls. All cardiovascular measurements, except blood testing, will be performed just once in healthy controls. They will not be treated with enalapril.

Contactpersonen

Publiek

Leiden Universitair Medisch Centrum
Derk-Jan ten Harkel
Postbus 9600

Leiden 2300 RC
The Netherlands
+3171-5262835

Wetenschappelijk

Leiden Universitair Medisch Centrum
Derk-Jan ten Harkel
Postbus 9600

Leiden 2300 RC
The Netherlands
+3171-5262835

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with a univentricular heart after palliation with the Fontan circulation from 8-18 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who already use ACE-inhibition.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2017
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46953
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6415
NTR-old	NTR6591
CCMO	NL59498.058.17
OMON	NL-OMON46953

Resultaten

Samenvatting resultaten

Harteveld LM, Blom NA, Terol C, Kuipers IM, Rammeloo LAJ, Hazekamp MG, Van Dijk JG, Ten Harkel ADJ. 3-month Enalapril Treatment in Pediatric Fontan Patients with Moderate to Good Systolic Ventricular Function. Am J Cardiol. 2021 Nov 10:S0002-9149(21)01007-9

Harteveld LM, Blom NA, Terol C, Van Dijk JG, Kuipers IM, Rammeloo LAJ, De Geus EJC, Hazekamp MG, Ten Harkel ADJ. Determinants of exercise limitation in contemporary paediatric Fontan patients with an extra cardiac conduit. Int J Cardiol. 2021 Oct 15;341:31-38.

Two other following (submitted)