Fontan-velocity study: Four-dimensional blood flow MRI analysis in patients with a Fontan circulation

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To visualize and quantify areas of dysfunctional flow in the TCPC and within the single ventricle in patients after a Fontan procedure and try to determine a relationship between these quantitative energetic parameters and adverse outcome.

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON46653

Source
ToetsingOnline

Brief title
Fontan-Velocity study

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Cardiac therapeutic procedures

Synonym
single ventricle, Univentricular heart

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Stichting Hartekind

Intervention

Keyword: 4D, Efficiency, Energy loss, Fontan

Outcome measures

Primary outcome

Echocardiographic parameters:

Cardiac index

MRI parameters:

Cardiac and Fontan tunnel:

Flow patterns and Energetics (energy loss)

Liver: Liver Multi-scan (fat, iron, fibrosis level)

Exercise test parameters:

peak oxygen uptake (VO2 max)

Stool parameter:

alpha-1 antitrypsin

Clinical parameters:

NYHA class

Episodes of PLE in history

Holter:

Arrythmias

Secondary outcome

Echocardiographic parameters:

ejection fraction, grading of AVV regurgitation, E/A ratio, propagation velocity

MRI parameters:

Cardiac:

End diastolic volume (EDV), End systolic volume (ESV), single ventricle

ejection fraction (EF), quantification of AVV regurgitation

Cardiac and Fontan tunnel:

Energetics (kinetic energy, turbulent kinetic energy, vorticity, wall shear

stress)

Exercise test parameters:

Peak heart rate, percentage of expected Watts.

Blood parameters:

complete blood count

liver function

kidney function

albumin and total protein

NT-proBNP, hs-TnT, GDF-15

Urine parameter:

Protein

Clinical parameters:

Time from Fontan operation

Study description

Background summary

Patients born with a functional univentricular heart are palliated via a staged approach leading to a Fontan circulation. The Fontan circulation provides a palliative solution by connecting the vena cavae directly to the pulmonary circulation without interposition of the heart, the so called total cavopulmonary connection. It is thought that an efficient flow of blood results in better outcome, as there is no heart which actively pumps blood into the pulmonary circulation.
Although early mortality has improved, the risk of complications such as protein losing enteropathy, plastic bronchitis, liver fibrosis and cirrhosis and reduced exercise capacity remains high.
Reduced efficiency of blood flow in Fontan patients have been an area of great interest as it is assumed to be important as there is no heart actively pumping the blood into the pulmonary circulation.

Study objective

To visualize and quantify areas of dysfunctional flow in the TCPC and within the single ventricle in patients after a Fontan procedure and try to determine a relationship between these quantitative energetic parameters and adverse outcome.

Study design

prospective cohort study

Study burden and risks

The possible complications after the Fontan procedure, which is nowadays performed on an age of 3-5 years, can occur early till late after the operation. It is therefore essential that patients with different timeframes

after correction are included in this study. If only adults were included in this study, the younger patients will probably not benefit from the findings of this study. Additionally, the Fontan operation has changed over time, with the modern ECC procedure being the preferred approach nowadays and has been implemented since 2000 in our hospital. This means that most of these patients are <20 years old and makes selection of only adults unfeasible.

There is no additional risk for patients in this study. All examinations are part of standard routine clinical practice in the follow-up of patients with a Fontan circulation.
In the future patients can benefit from entry into this study, as results from this study can possibly identify which patients are at increased risk of complications and lead to potential better treatment possibilities in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients with an intact Fontan-TCPC circulation performed at the LUMC
>8years of age
No contra-indications for exercise test
No contra-indications for MRI examination

Exclusion criteria

Claustrophobia
Contraindication for MRI
<8 years old
Pacemaker in situ

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO Date:	20-08-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
CCMO	NL63854.058.17