Renal Hemodynamics in patients with a univentricular Fontan circulation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON53480

Source
ToetsingOnline

Brief title
Fontan-RH

Condition

- Cardiac and vascular disorders congenital
- Nephropathies

Synonym
Fontan circulation, Univentricular circulations

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Renal function, Sonography, Univentricular heart, Venous congestion

Outcome measures

Primary outcome

The primary endpoint will be the difference in iRVF pattern measured via renal sonography, renal function (eGFR) and renal damage (urine albumin, L-FABP and cystatin C concentrations) between patients with a Fontan circulation vs. healthy age and sex matched controls.

Secondary outcome

The secondary endpoints will include the following:

- Identify the prevalence of different iRVF patterns in patients with a Fontan circulation assessed with renal ultrasound.
- Estimated glomerular filtration rate determined by serum creatinine and plasma cystatin C.
- Concentration of urine albumin, L-FABP and cystatin C.
- Difference of eGFR between iRVF patterns.
- Difference in urine albumin, L-FABP and cystatin C concentration between iRVF-patterns.
- Correlation of eGFR, urine albumin L-FABP and urine cystatin C to venous discontinuity index (VDI) and/or venous impedance index (VII).

Study description

Background summary

Discontinuous intrarenal venous flow (iRVF) patterns are associated with poor renal function and diuretic response in patients with biventricular circulation who have elevated venous pressures. People with univentricular circulation, by definition, have an elevated venous pressure. However, the role of iRVF patterns on renal function in univentricular circulations has never been established.

The hypothesis of this study is that, in patients with univentricular circulation the iRVF patterns will be discontinuous compared to healthy subjects and that the iRVF patterns will be associated with a decreased renal function.

Study objective

The primary objective is to determine whether iRVF patterns and renal damage/function are different in patients with a Fontan circulation compared to age and sex-matched healthy controls.

The secondary objectives are to
- Identify the prevalence of different iRVF patterns in patients with a Fontan circulation.
- Determine whether renal function as determined by estimated glomerular filtration rate is different between iRVF patterns.
- Determine whether renal damage as assessed with glomerular and tubular damage markers is different between iRVF patterns.
- Determine whether iRVF as defined by the venous discontinuity index (VDI) or venous impedance index (VII) correlates to estimated glomerular filtration rate in Fontan patients.
- Determine whether iRVF as defined by the venous discontinuity index (VDI) or venous impedance index (VII) correlates to a degree of renal damage as assessed with glomerular and tubular damage markers in Fontan patients.

Exploratory objectives include
- Whether the age of Fontan-patients is different between different iRVF-patterns
- Whether the age of Fontan-patients is associated with either VDI or VII.

Study design

The proposed study is a single centre, cross-sectional observational case-control study, including 40 patients with a univentricular circulation and 40 healthy controls.

Study burden and risks

Participating test subjects will be asked to pay a one-time visit to the University Medical Center Groningen (UMCG).
For patients with a univentricular circulation, the study visit will, if possible, take place during their annual visit to the UMCG's (pediatric) cardiology outpatient clinic. For a brother or sister of a Fontan patient participating in the healthy subject study, an appointment will be made to schedule the same day as the patient.

Prior to the testing visit, patients will be asked to collect 24-hour urine samples. During the testing visit, they will have to undergo a renal sonography and a venapuncture. The risks associated with these procedures are very limited, rare and include bleeding and infection for venipuncture and contact dermatitis for the gel used during the sonography.

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)

Inclusion criteria

patients:
1. Able and willing to give written informed consent
2. Male and female subjects with age >=12 years
3. Palliated with either of the four following *Fontan* circulations
a. Atrio-pulmonary connection
b. Lateral tunnel cavopulmonary connection (TCPC)
c. Extra-cardiac cavopulmonary connection (TCPC)
d. Kawashima circulation

controls:
1. Able and willing to give written informed consent
2. Male and female subjects with age >=12 years

Exclusion criteria

patients:
1. Patients on (intermittent or continuous) haemodialysis
2. Estimated glomerular filtration rate < 45 ml/min/1.73m2
3. Female patients pregnant at the time of inclusion and or study visit

controls:
1. Diagnosis of any cardiovascular disease in medical history
2. Diagnosis of any renal disease in medical history
3. Female subjects pregnant at the time of inclusion and or study visit

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-08-2024
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	18-10-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL82753.042.22