Quantifying Electropathology in Paediatric Patients with Congenital Heart Disease:
an intra-operative epicardial mapping study

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To quantify the role of different abnormal loading conditions on atrial and ventricular electropathology in paediatric patients with CHD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON49092

Source
ToetsingOnline

Brief title
FANTASIA

Condition

- Cardiac arrhythmias
- Cardiac and vascular disorders congenital
- Cardiac therapeutic procedures

Synonym
congenital heart defect, Congenital heart disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: congenital heart disease, epicardial mapping, sinus rhythm

Outcome measures

Primary outcome

Electrophysiological parameters obtained from epicardial mapping, to measure the extent of electropathology. Parameters include e.g. pattern of activation, conduction delay or block, conduction velocity, voltage distribution. These parameters will be compared between the different atrial and ventricular sites and correlated to clinical characteristics.

Secondary outcome

Not applicable.

Study description

Background summary

Patients with congenital heart disease (CHD) are prone to development of cardiac tachyarrhythmias. Important factors associated with this increased risk include scar tissue and suture lines from prior cardiac surgery and longstanding volume or pressure overload, leading to development of electropathology. Structural remodeling of myocardial tissue underlies development of complex electrical conduction disorders (i.e.: electropathology), which in turn predispose to development of atrial and ventricular tachyarrhythmias.
The majority of patients with hemodynamically significant CHD undergo surgical correction or palliation at young age. Despite the relatively short duration of volume/pressure overload, these patients still develop atrial tachyarrhythmias during long-term follow up. The role of early and short standing volume/pressure overload during the first weeks, months or years of life on

development of electropathology is unknown.

Study objective

To quantify the role of different abnormal loading conditions on atrial and ventricular electropathology in paediatric patients with CHD.

Study design

The FANTASIA study is a prospective observational study, which includes the following study procedures: 1) intraoperative atrial and ventricular epicardial mapping during sinus rhythm, 2) storage of postoperative continuous rhythm recordings that are carried out according to standard care.

Study burden and risks

For participants of this study there are no direct benefits. Neither the patient, nor the investigators are in any way compensated for their participation with regards to this study. The risks associated with participation are known to be negligible, since epicardial mapping using the non-investigational product (see Medical Device Dossier) in over 500 patients in previous METC-approved studies (MEC 2010-054, MEC 2014-393) did not cause any complications. Since May 2020, epicardial mapping according to the FANTASIA protocol has been routinely implemented in paediatric patients in the Erasmus MC. First experience has demonstrated the safety of the mapping procedure in paediatric patients, as no complication occurred during the mapping procedure.[in press ICVTS] Epicardial mapping will only be performed during the patient's own natural rhythm. The burden of participation in the FANTASIA study is minimal. The duration of the surgical procedure is minimally prolonged by the epicardial mapping procedure with an estimate of 10 minutes. With regard to the use of postoperative continuous rhythm recordings in the FANTASIA study, the only difference with standard care is that the rhythm recordings are stored. Hence, this will have no effect whatsoever on the usual postoperative course and treatment.
Group-relatedness exists because the study cannot be performed in adult patients with CHD, since the role of early and short standing volume/pressure overload cannot be studied in these adult patients due to the presence of aging and longstanding volume/pressure overload as major confounding factors.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients aged <18 years with congenital heart disease (abnormal loading condition), scheduled for elective cardiothoracic surgery for congenital heart disease.

Exclusion criteria

Use of inotropic agents
Undergoing redo cardiac surgery predisposed for excessive adhesions

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2020
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Multi-electrode array (MEA) type 192p-TUD-V1.3
Registration:	No

Ethics review

Approved WMO Date:	30-01-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	14-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL70950.078.19