Quantifying Electropathology in Adult Patients with Congenital Interatrial Communications
an endocardial mapping study

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to quantify atrial electropathology of the endocardium in adult patients with CHD and to correlate clinical characteristics, atrial volume, electropathology, atrial ectopy and features of pre- and post-procedural atrial fibrillation.

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

Summary

ID

NL-OMON51978

Source
ToetsingOnline

Brief title
ATLANTIS

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: Atrial fibrillation, Congenital heart disease, Endocardial mapping

Outcome measures

Primary outcome

Quantification of electrophysiological parameters obtained from endocardial mapping that determine the degree of electropathology: conduction block, conduction delay, conduction velocity, signal morphology (voltage, fractionation). These parameters will be correlated with electropathology, atrial ectopy, atrial volume, clinical characteristics and features of pre- and post-procedural atrial fibrillation.

Secondary outcome

N.a.

Study description

Background summary

Patients with congenital heart disease experience atrial fibrillation more often and at a younger age than patients without congenital heart disease. In addition, treatment of atrial fibrillation is more difficult in patients with congenital heart disease.

Correction of the cardiac defect has decreased the incidence of atrial fibrillation in this population, however it does not prevent atrial fibrillation. Patients with congenital heart disease still develop more frequently atrial fibrillation than patients without congenital heart disease. Pre-existent disorders in the electrical conduction, caused by volume overload due to the cardiac defect, are thought to play a role in the development of

this arrhythmia.

Study objective

to quantify atrial electropathology of the endocardium in adult patients with CHD and to correlate clinical characteristics, atrial volume, electropathology, atrial ectopy and features of pre- and post-procedural atrial fibrillation.

Study design

The ATLANTIS study is designed as an interventional multicenter study

Intervention

Endocardial mapping during sinus rhythm and programmed electrical stimulation before and after endovascular closure of the cardiac defect.

Study burden and risks

For participants in this study there are no direct benefits. Neither the patient, nor the investigator are in any way compensated for their participation with regards to this study. The risks associated with participation are known to be negligible, since endovascular mapping and programmed electrical stimulation are performed routinely in standard electrophysiological studies for the treatment of arrhythmia. For placement of the catheters an additional venous access needs to be made in the groin. The risks of such electrophysiological procedures are minimal. Programmed electrical stimulation could induce atrial fibrillation. Theoretically atrial fibrillation could lead to hemodynamic instability, often seen in patients with severe heart failure. These patients are excluded from participating in this study. Patient's vitals will be monitored closely throughout the procedure. Consequently, if atrial fibrillation is induced, patient's heart rhythm will immediately be converted to sinus rhythm with cardioversion. Potentially the closure device could be dislocated during the electrophysiological study. However, large defects at high risk for this complications will be excluded. Measurements will be terminated immediately if such a scenario occurs. The additional procedural time, and thus the general anaesthesia time, will be lengthened by approximately 15-20 minutes. The additional anaesthesia time does not increase the risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

>=18 years;
Scheduled for elective endovascular closure of atrial septal defect or patent foramen ovale

Exclusion criteria

Paced atrial rhythms
Pacemaker/ internal cardiac defibrillator (ICD)
Hemodynamic instability
Presence of assist devices
Use of inotropic agents
Emergency endovascular cardiac procedures
Left ventricle ejection fraction < 30%
Severe kidney or liver failure
Receiving local anaesthesia

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2022
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	01-04-2022
Application type:	First submission
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	NL78227.078.21