Serial biomarker AssesMent in adults after percutaneous clOSure of the Atrial septal defect

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Primary Objective: Identification of patient characteristics, echocardiographic measurements and biomarkers that can contribute to a better selection of patients that benefit from percutaneous ASD closure at adult age. Secondary Objectives:-...

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

Summary

ID

NL-OMON47308

Source
ToetsingOnline

Brief title
SAMOSA

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Atrial septal defect

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: Adults, Atrial septal defect, Biomarkers, Congenital heart disease

Outcome measures

Primary outcome

Non-responders after percutaneous ASD closure will be defined as:

- Sustained echocardiographic RV dysfunction after one year (eyeballing, right ventricular fractional area change <35%, TAPSE <17 mm);

- Sustained high RV pressures after one year (measured by tricuspid regurgitation maximal velocity >2.8 m/s).

Secondary outcome

The serial evolution of several variables will be investigated, in order to gain more insight in the pathophysiological consequences of volume-load reduction on the right heart:

- Biomarkers: NT-proBNP and other biomarkers that may arise to be potentially important during the execution of this study.

- Conventional echocardiography: RV dimensions, RV systolic function, LV dimensions, LV systolic and diastolic function;

- Speckle tracking echocardiography: global and segmental longitudinal strain of the RV and LV.

Study description

Background summary

The atrial septal defect (ASD) is a common congenital cardiac anomaly, accounting for approximately 10% of congenital cardiac anomalies.(1) Increased

pulmonary flow caused by left-to-right shunting can lead to pulmonary arterial hypertension in a subset of patients.(2) Left untreated, the consequent increase in pulmonary vascular resistance may cause progressive deterioration of right ventricular (RV) function and eventually death.(3,4) Therefore, ASD closure is performed in patients with significant shunts causing RV volume overload, unless specific contra-indications are present.(5)

As ASDs are usually detected and closed in childhood, less is known about the effects of ASD closure in adult patients. Previous studies have already shown that the adult heart continues to hold an ability to reverse remodel after removing the volume-overload, as right atrial and ventricular volumes were significantly smaller after ASD closure.(6) Presumably, these reverse remodelling processes are accompanied by subtle molecular changes in the heart. It remains unknown which biomarkers can best reflect these processes and to what extent biomarkers can contribute to the selection of patients that may benefit from ASD closure at adult age.

This observational, longitudinal cohort study aims to perform serial biomarker measurements in adult patients before, short-term after and long-term after percutaneous ASD closure. This will gain more insight in the pathophysiological consequences of volume-load reduction on the right heart. Moreover, this might contribute to a better selection of patients that actually benefit from ASD closure at adult age.

Study objective

Primary Objective:
Identification of patient characteristics, echocardiographic measurements and biomarkers that can contribute to a better selection of patients that benefit from percutaneous ASD closure at adult age.

Secondary Objectives:
- Identification of biomarkers that reflect reverse or adverse cardiac remodelling processes after percutaneous ASD closure in adult patients.
- Detect echocardiographic changes after percutaneous ASD closure in adult patients.

Study design

This is a prospective, observational cohort study with invasive measurements (drawing of blood samples). All adult patients who are scheduled to undergo percutaneous ASD closure in our center will be approached. Study inclusion implies that blood samples will be drawn during or right before the procedure, 1 day after the procedure, 3 months and 1 year after the procedure. During the 3 months and 1-year follow-up, patients already visit the outpatient cardiology clinic for a regular follow-up visit. Drawing of blood samples will be combined

with these outpatient follow-up visits. ECG and echocardiography measurements, performed as part of routine clinical care during these outpatient visits, will be additionally collected in our database. For each study subject the total study duration will be one year.

Study burden and risks

For this study, blood samples (7 tubes, 44 mL blood) will be obtained at four different time points. All other investigations in this study are part of routine clinical care. Therefore, risks for the patients can be considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Scheduled to undergo percutaneous ASD closure in the Erasmus MC;
- Capable of understanding and signing informed consent.

Exclusion criteria

- Patients living abroad or who are not Dutch speaking;
- Age <18 years;
- Renal impairment (serum creatinine >200 umol/L);
- Failure of percutaneous ASD closure due to procedural problems.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	17-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-10-2018
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	NL53428.078.15