The Relationship between Atrial SEptal Defects (ASD) And BRonChial Hyperresponsiveness (SEARCH); Towards understanding the mechanism of dyspnea in adult ASD patients.

Published: 05-10-2017
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The aim of this study is to investigate the relationship between atrial septal defects and airway responsiveness before and after percutaneous closure.

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

Summary

ID

NL-OMON44433

Source
ToetsingOnline

Brief title
SEARCH

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Bronchial disorders (excl neoplasms)

Synonym
airway hyperresponsiveness; an airway reaction to a non-specific trigger (methacholine) that would normally not excite significant airway narrowing.

Research involving

Human

Sponsors and support

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

Intervention

Keyword: airway hyperersponsiveness, atrial septal defects, dyspnea, percutaneous device closure

Outcome measures

Primary outcome

Primary ~: presence and extent of airway responsiveness at follow-up after

percutaneous ASD closure.

Secondary outcome

Secondary ~: difference in airway responsiveness between pre-procedural and

post-procedural measurements.

Study description

Background summary

Secundum atrial septal defects (ASDs) are the second most common congenital heart defects. Appropriate and timely diagnosis and treatment prevents complications of long-standing right ventricular volume overload such as pulmonary hypertension and right-sided heart failure. Better understanding of ASD-based dyspnea may help to distinguish it from other (non-)cardiac causes of dyspnea, potentially preventing patients* and physicians* delay in diagnosing ASD. Although seen as a clinical coincidence, adult ASD patients often report dyspnea with wheezing, chest tightness and cough that may mimic bronchial asthma. Airway hyperresponsiveness is a common feature of bronchial asthma and characterizes by more sensitive and increased airway narrowing to nonspecific stimuli that normally lead to little or no airway response. Both experimental and clinical studies have reported its presence in mitral valve disease and ischemic cardiomyopathy. ASD-based left-to-right shunting and the resulting flow-mediated pulmonary vascular distention may be related to asthma-like

symptoms. If so, clinical awareness thereof can guide physicians to correctly diagnose ASD in adults.

Study objective

The aim of this study is to investigate the relationship between atrial septal defects and airway responsiveness before and after percutaneous closure.

Study design

Observational cohort study. Patients eligible for the study will undergo a single lung function test consisting of spirometry and methacholine provocation. Patients* baseline characteristics and documented symptoms and lung function will be retrospectively studied to investigate the effect of percutaneous closure on airway responsiveness.

Study burden and risks

No study-specific benefits and risks are anticipated for the subjects in the study population.

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

*Adult age (> 18 years)
*Secundum ASD successfully closed using a septal occluder
*Available spirometry and methacholine provocation test results from before percutaneous ASD closure.

Exclusion criteria

Absolute contraindications
o Severe airflow limitation (FEV1 <50% predicted or <1L)
o Myocardial infarction or stroke in last three months
o Uncontrolled hypertension (systolic BP >200mmHg or diastolic BP >100mmHg)
Relative contraindications:
o Moderate airflow limitation (FEV1 <60% predicted or <1.5L)
o Inability to perform acceptable-quality spirometry
o Pregnancy
o Nursing mothers

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-10-2017

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62746.018.17