Evaluation of the VU-AMS device during follow-up of children with congenital heart disease

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To evaluate the clinical usefulness of the VU-AMS in pediatric cardiology.To validate and improve the measures of stroke volume from the VU-AMS device in a clinical population. VU-AMS stroke volume measures will be compared with stroke volume...

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

Summary

ID

NL-OMON40526

Source
ToetsingOnline

Brief title
Evaluation of the VU-AMS device in congenital heart disease

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Congenital heart disease, heart disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ambulatory assessment, Cardiac autonomic nervous system, Pediatric cardiology

Outcome measures

Primary outcome

The most important study variables are:

Stroke volume (SV): the amount of blood leaving the heart with a single heartbeat.

Pre Ejection Period (PEP); The time between the onset of the electrical activation of the ventricles and the mechanical activation of the ventricles (opening of the aortic valve). This is a measure of sympathetic activity and contractility of the heart muscle.

Respiratory sinus arrhythmia (RSA); this is a naturally occurring variation in heart frequency during a breathing cycle. RSA is the difference in time between the shortest two successive heart beats and the slowest.

Left ventricular enddiastolic volume as measured by echocardiography and MRI

Maximal oxygen consumption as measured by a maximal exercise test

Secondary outcome

None.

Study description

Background summary

The VU-AMS (Vrije Universiteit Ambulatory Monitoring System) is developed at the VU University and is designed to record four different signals: the electrocardiogram, impedance cardiogram, movement, and hand skin conductance. Until today, this device is mainly used to study stress and emotion, both in

laboratory and naturalistic environments. The current study is designed to evaluate the clinical usefulness of the VU-AMS device in pediatric cardiology. Daily variations in stroke volume and cardiac autonomic nervous activity will be measurements of interest. These will be compared to values obtained in a previous study done in a healthy age matched control group.

Detailed echocardiogram, an MRI and exercise testing will be performed and subsequently, the VU-AMS device will be worn for 24 hours. Stroke volume measures from the VU-AMS device and echocardiography will be compared. Also, 24 hour fluctuations in stroke volume and autonomic nervous activity will be studied. Changes in autonomic nervous activity will be related to exercise tolerance

Study objective

To evaluate the clinical usefulness of the VU-AMS in pediatric cardiology.

To validate and improve the measures of stroke volume from the VU-AMS device in a clinical population. VU-AMS stroke volume measures will be compared with stroke volume measured by echocardiography.

To compare reference values obtained in a normal population of children for sympathetic- and parasympathetic nervous indices, and stroke volume changes during rest and exercise.

To study the relationship between daily variation in autonomic nervous system and stroke volume indices and exercise capacity.

Study design

The design of the study is observational. 120 children with a congenital heart disease with an age range of 8-18 years will be recruited from the policlinic.

Detailed echocardiography will be performed, including 2- and 3-dimensional strain and tissue Doppler imaging, jointly with VU-AMS recording to test the validity of stroke volume measures by the VU-AMS in this population. An MRI and a symptom limited exercise testing will be performed. Subsequently, the VU-AMS device will be used to measure 24 hour fluctuations in cardiac sympathetic- and parasympathetic nervous activity and stroke volume in all children. An i-pod or i-phone running a program to keep an electronical diary designed at the VU University will be used to monitor activities and posture and location during the 24 hour ambulatory measurement.

In case of abnormal findings for which medical act or adjustment of therapy is deemed necessary, this will be discussed with parents and child and the doctor will be informed.

Study burden and risks

All children will undergo echocardiogrphy during a 30-minute period and will wear the VU-AMS device during 24 hours. During that period there are no restrictions except from bathing and swimming. A cardiac MRI will be performed and a symptom limited exercise test will be performed as well.

There are no risks in these examinations. Echocardiography, MRI and exercise testing are part of standard follow-up in these patient groups.

There is a huge amount of experience with the above mentioned evaluations in children. Usually there are no problems in performing these studies.

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 after repair of a ventricular septal defect (VSD), patients after coarctectomy, patients after arterial switch operation for transposition of the great arteries, patients with a univentricular heart after Fontan completion.

Exclusion criteria

Comorbidity

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL47467.058.14