Evaluation of the VU-AMS device in pediatric cardiology

Published: 10-12-2013
Last updated: 23-04-2024

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. VU-AMS stroke volume measures will be compared with stroke volume measured by echocardiography.To...

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

Summary

ID

NL-OMON38626

Source
ToetsingOnline

Brief title
Evaluation of the VU-AMS device in pediatric cardiology

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, 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.

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.

In order to do this, we first need to gather reference values and validate the

device on several modalities that are of interest in the clinical evaluation of pediatric cardiac patients. Stroke volume and cardiac autonomic nervous activity will be measurements of interest.

Therefore, 150 healthy children will be recruited from the outpatient clinic (1-4 years), primary schools (4-12 years) and secondary schools (12-18 years) in Leiden. Detailed echocardiogram 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.

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. VU-AMS stroke volume measures will be compared with stroke volume measured by echocardiography.

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

Study design

The design of the study is observational. 150 healthy children with an age range of 1-18 years will be recruited. Children from 1-4 years will be recruited from the outpatient department of pediatric cardiology. Those who have an innocent murmur or other complaints that turns out to be unrelated to a cardiac disorder can be included. Children from 4-12 years will be recruited from a primary school, and from 12-18 years from a secondary school. Children who have any chronic disorder or use medication cannot be included. Five to ten children of each year-group will be included.

The children will 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. 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. Reference values in a healthy population will be developed and the VU-AMS will be validated.

Study burden and risks

All children will undergo echocardiogarphy 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.

Since we are studying the normal variability and usefulness of the VU-AMS device in the pediatric population it is only possible to answer these questions by studying children.

There is a huge amount of experience of echocardiography and 24-hour Holter monitoring 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

Healthy, aged between 1 and 18

Exclusion criteria

Heart disease, any chronic disorder, medication use

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	10-12-2013
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	NL46086.058.13