Normal values for echocardiography with speckle tracking and biomarkers in a healthy population.

Published: 07-11-2013
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To obtain normal values for speckle-tracking derived parameters and for biomarkers in healthy volunteers aged from 20 till 70 years.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON39015

Source
ToetsingOnline

Brief title
The NAVIGATOR study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart function, ventricular function

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: Biomarkers, Echocardiography, Myocardial deformation, Speckle tracking

Outcome measures

Primary outcome

Determining normal values of LV and RV radial, circumferential and longitudinal strain, and LV rotation and twist by speckle-tracking echocardiography in various age groups.

Secondary outcome

Determining normal values of the biomarkers NT-proBNP, hsCRP, hsTnT, IL-1, IL-6, TNF-α, MMP-2, MMP-9, TIMP-1, GDF-15, HSP-70 in various age groups.

Study description

Background summary

Conventional two-dimensional echocardiography is a valuable tool in cardiology, especially for the assessment of global systolic and diastolic function in for instance patients with congenital heart disease or cardiomyopathy. The most widely used parameter for describing left ventricular (LV) systolic function in a clinical setting is fractional shortening. However, fractional shortening only measures LV systolic function along a single interrogation line, potentially missing regional systolic dysfunction. The right ventricle (RV) is even more difficult to visualize and quantify. Recent advances in echocardiography have lead to the development of techniques that measure global and regional myocardial function more accurately than the conventional echocardiography. The so-called speckle-tracking 2D-echocardiography and 3D-echocardiography provide much more accurate information on tissue deformation, such as myocardial strain and strain rate (SR). There are various vendors for these ultrasound systems and software. Other new and possibly additional measurements are the new biomarkers. These could be used to monitor subtle molecular changes in the heart that reflect and possibly predict adverse changes before they become clinically apparent. At present, normal values for biomarkers and speckle-tracking derived strain measured with the software used in our hospital are scarce, which hampers the interpretation of these values in

patients with heart disease.

Study objective

To obtain normal values for speckle-tracking derived parameters and for biomarkers in healthy volunteers aged from 20 till 70 years.

Study design

A prospective, observational cohort study.

Study burden and risks

Echocardiography and venous punction are routinely performed in Erasmus MC. Echocardiography is a non-invasive imaging technique; venous punction is invasive, but minimally and will be performed by experienced employees. There are no known significant safety issues.

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

Healthy adults between the age of 20 and 70 years.
Capable of understanding and signing informed consent.

Exclusion criteria

Cardiovascular disease.
Cardiovascular risk factors, such as hypertension, diabetes mellitus, hypercholesterolaemia.
Non-Dutch speaking.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2014
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	07-11-2013
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	NL45681.078.13