Evaluation of the potential of Real-Time 3-Dimensional echocardiography in the assessment of right ventricular function in patients with congenital heart disease: comparison of RT-3D echo with MRI.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON33891

Source
ToetsingOnline

Brief title
RT 3D echo vs MRI for assessment of RV function in patients with CHD.

Condition

- Cardiac and vascular disorders congenital

Synonym
congenital heart defects, Congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: 3D echo, congenital, MRI, right ventricle

Outcome measures

Primary outcome

Difference between MRI and RT 3-D echo measurements of RV volumes, proportion of patients in which a RT 3-D echo assessment of RV volumes is feasible, improvement of analysis with the use of echo-contrast, duration of the data acquisition (MRI compared with RT 3-D echo), duration of data analysis.

Secondary outcome

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Study description

Background summary

Right ventricular dysfunction as a clinical problem occurs frequently in the population of patients with congenital heart disease. Consequently, periodical assessment of right ventricular function is indicated in a large proportion of the patients with congenital heart disease. So far, MRI is the method of choice for assessment of right ventricular function. The current MRI technique has several disadvantages for its use for assessment of right ventricular function in patients with congenital heart disease: the acquisition time for cardiac MRI is long (30- 60 minutes) and off-line analysis is very time consuming (often > 1 hour). Both acquisition and analysis require expert knowledge in the field of congenital heart disease, an expertise not commonly available and hardly ever present in a radiology department, necessitating the presence of a cardiologist or paediatric cardiologist during the whole process of data acquisition and analysis. Recently, transthoracic Real-Time 3-Dimensional Echocardiography (RT 3-D echo) became commercially available. RT 3-D echo has the potential to encompass the entire right ventricle in one ultrasound dataset. It is

demonstrated that, in selected cases and in experimental setting, it is possible to acquire the right ventricle and its volume-changes throughout the cardiac cycle within a few heartbeats with the real-time 3-D technique. However, there are no published data about the use of RT 3-D echocardiography for RV volumes in unselected patients in a clinical setting. The only (unpublished) data seems promising in this respect. If it could be demonstrated that it is feasible to assess right ventricular function reliably by 3-D echocardiography, an alternative for MRI becomes available, which is cheaper and has a much shorter acquisition time.

Study objective

The aim of this study is assessment of right ventricular function: a comparison between MRI and real-time 3-D echocardiography (RT 3-D echo). We have the following research questions:
1) Is assessment of right ventricular (RV) function with RT 3-D echo in an optimal echo setting not inferior to assessment with MRI?
2). What is the proportion of patients in which RT 3-D echo does lead to a data set with insufficient quality, precluding RV function analysis?
3) What is the proportion of patients/ healthy adults in which RT 3-D echo with use of echo-contrast does lead to a data set with insufficient quality, precluding RV function analysis?

Study design

125 patients who will undergo a MRI for assessment of right ventricular function will have a 3-D echo study within 2 hours of the MRI examination or patients who will undergo a regular 2-D echo will undergo both a 3-D echo and MRI. Twenty adults patients of this group will be asked permission to use echo-contrast. Moreover, 50 healthy adults will undergo 3-D echo and MRI and half of them will be asked to use echo-contast. The investigators are blinded for the results of the other examination. Two independent observers will examine the MRI data and 2 other independent observers will analyse the echo data.

Study burden and risks

In case the MRI takes place on clinical grounds, the time investment per patient will be 15 minutes for the 3D echo. In case both 3D echo and MRI take place on research grounds, the time investment will be 45-60 minutes. The use of echo-contrast leads in 0.031% of the cases to severe side effects, so there will always be a doctor present during the examination that can use mediction to counteract the eventuel adverse effect.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients or healthy adults (definition see above) with a signed informed consent.

Exclusion criteria

Patients or healthy adults that do not give informed consent.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2007
Enrollment:	175
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-09-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-11-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	18-12-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-06-2009
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	NL16658.078.07