Postoperative evaluation of ventricular function by tissue Doppler and speckle tracking echocardiography after surgery for congenital heart disease

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The objective of the present study is the evaluation of ventricular function in patients with congenital heart defects by means of newly developed echocardiographic techniques as tissue doppler and speckle traking stran rate echocardiography. Since...

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

Summary

ID

NL-OMON32759

Source
ToetsingOnline

Brief title
Tissue Doppler and speckle tracking echocardiography

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
congenital 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: Congenital heart disease, Speckle Tracking, Tissue Doppler

Outcome measures

Primary outcome

The primary study parameters are the changes in echocardiographic values that

will be obtained before and after surgical correction of a congenital heart

defect.

Secondary outcome

Not applicable

Study description

Background summary

Most patients with congenital heart disease nowadays survive operative correction However, long-term consequences of the congenital heart defect and its correction are the persistence of residual defects, the occurrence of rhythm disorders and the presence of heart failure. These effects will influence daily functioning, and many studies show differences in quality of life and decreased exercise tolerance in these patient groups. Although most significant changes develop during long-term follow-up, it is unclear if intrinsic properties of the cardiac muscle, or the effect of the first surgical correction already predict long-term deterioration. Although the use of cardiopulmonary bypass can lead to deterioration of ventricular performance, its contribution to longer-term ventricular performance is as yet unknown. One of the most prominent features already present immediately after surgical correction is the presence of right bundle branch block on the

electrocardiogram in many patients. This
may indicate the presence of ventricular dyssynchrony already at an early stage. In this study we will evaluate ventricular function after surgical correction for congenital heart disease. By using
new echotechniques as tissue Doppler imaging and speckle tracking it will be possible to find subtle changes in
both diastolic and systolic ventricular function perioperatively. We will therefore perform detailed echocardiography
preoperatively, 1 and 3 days, 1 week and 3 months postoperatively. We expect that changes in ventricular function
will be largest immediately postoperatively, and will partially resolve during recovery. It is expected that some
changes will persist during the follow-up period. In the past we performed several studies in patients during
long-term follow-up. From these studies it became already clear that most patients after correction for congenital
heart disease show differences in echocardiographic parameters, and changes in exercise tolerance. It is,
however, unclear if these changes develop during growth and follow-up or are already present immediately
postoperatively. In the present study we will try to answer these questions.

Study objective

The objective of the present study is the evaluation of ventricular function in patients with congenital heart defects by means of newly developed echocardiographic techniques as tissue doppler and speckle traking stran rate echocardiography. Since we will study patients both before surgical correction as well as afterwards the influence of the operation with cardiopulmonary bypass can be studied. By means of studies obtained 3 months later we can differentiate between effects that are temporarily present after operation and long-term effects.

Study design

We will perform detailed echocardiography including tissue doppler and speckle tracking strain rate in patients before and after surgical correction of their congenital heart defect. Patients will be studied before the surgical correction, 1 and 3 days afterwards, and 1 week and 3 months later. Both diastolic and systolic function will be studied.

Study burden and risks

All echocardiographic studies will be performed in patients that otherwise had to undergo these studies as well. Since in the present study we will measure some extra parameters, this will increase the time of each echocardiographic

study by 5-10 minutes. Since all echocardiographic studies are completely noninvasive these extra minutes will be associated with only minimal burden.

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

Surgical correction of a congenital heart defect below the age of 18 years

Exclusion criteria

Insufficient echocardiographic window

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):	05-01-2009
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	11-11-2008
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	NL23860.058.08