Functional outcome and quality of life in adult congenital heart disease patients with prosthetic valves*

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To investigate the relation between characteristics of valve prosthesis on functional outcome andquality of life in adult patients with CHD. To investigate the prevalence and predictors of PPM in a population withCHD. To investigate the incidence of...

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

Summary

ID

NL-OMON32722

Source
ToetsingOnline

Brief title
Prostava

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Cardiac therapeutic procedures

Synonym
prosthetic heart valves in congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ICIN en NHS

Intervention

Keyword: valves - prosthesis - complications - quality of life - exercise

Outcome measures

Primary outcome

Primary outcomes are VO2max and quality of life.

Secondary outcome

Secondary outcomes are the prevalence of PPM and the incidence of valve related

complications.

Study description

Background summary

In patients with congenital heart disease (CHD), often mechanical or biological prosthetic valves are
implanted. These patients differ from adults who have prosthetic valves implanted for acquired valve disease (e.g.
differences in age, lifestyle, variety of valve location). The prevalence of pulmonary and tricuspid prosthetic valves
is high. The prevalence of prosthesis-patient-mismatch (PPM) is probably high because often valves were
implanted during childhood. In patients with acquired valve disease PPM is associated with decreased survival and
increased incidence of heart failure. Data about the prevalence of PPM in adults with CHD are lacking. The
probable high prevalence of PPM and the complicated history of many CHD patients may predestinate them for
complications such as heart failure and arrhythmias. The influence of prosthetic valve characteristics (type,
location, size/PPM) in adults with CHD on functional outcome and quality of life has however not been
investigated. Moreover, data about the long-term complications of prosthetic valves in adults with CHD are scarce.
For example, in the pulmonary position usually biological valves are implanted because of a presumed high

incidence of thrombo-embolism associated with mechanical valves, but scientific evidence confirming this
presumption is lacking.

Study objective

To investigate the relation between characteristics of valve prosthesis on functional outcome and
quality of life in adult patients with CHD.
To investigate the prevalence and predictors of PPM in a population with CHD.
To investigate the incidence of valve prosthesis-related complications in a population with CHD
(re-operation, valve thrombosis, bleeding complications, hemolysis, paravalvular regurgitation, endocarditis,
arrhythmias, pregnancy-related complications, heart failure).
To investigate the relation between prosthesis related complications and valve type.

Study design

Patient files of CHD patients with prosthetic valves identified from the CONCOR database will be studied for past
medical history including surgical procedures and for the occurrence of valve-related complications. The
cross-sectional evaluation comprises history, physical examination, VO2max, quality of life questionnaires,
echocardiogram including prosthetic valve area, MRI (ventricular volumes and mass), laboratory evaluation
(including NT-pro-BNP).

Study burden and risks

As all investigations are routine investigations in this population, no risk is involved. Investigations will be scheduled as much as possible combine with an already scheduled visit. maximum extra time for each patients is one day. Patients may indirectly benefit from the study resulsts, because our results may influence the choice of valve prosthesis, the indication for more extensive surgery (e.g. annulus enlargement) and the indication for re-operation in patients with prosthesis-patient-mismatch.

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

Included in concor database, congenital heart disease, valve prosthesis 9all required)

Exclusion criteria

Inability to comply with examinations (quality of life questionnaire and exercise test)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2010
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	6723
CCMO	NL29965.042.09