Functional outcome and quality of life in adult congenital heart disease patients with prosthetic valves (PROSTAVA-study).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21400

Source
NTR

Brief title
PROSTAVA

Health condition

Prosthetic Valves; Adult Congenital Heart Disease

Sponsors and support

Primary sponsor: Netherlands Heart Foundation
University Medical Center Groningen
ICIN
Source(s) of monetary or material Support: Netherlands Heart Foundation

Intervention

Outcome measures

Primary outcome

1. VO2 max;

2. Quality of life.

Secondary outcome

Prosthetic valve related compliations.

Study description

Background summary

Background:
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.

Hypothesis:

1. Prosthetic valve characteristics (type; location; size resulting in the presence/absence of PPM) are related to functional outcome and quality of life;

2. The incidence/spectrum of prosthetic valve-related complications in adults with CHD differs from populations with acquired valve disease.

Objective:

Main objective:
To investigate the relation between characteristics of valve prosthesis on functional outcome and quality of life in adult patients with CHD.

Secondary objectives:
To investigate the prevalence and determine predictors of PPM in an adult population with CHD.
To retrospectively investigate the prevalence of valve prosthesis-related complications in an adult population with CHD and a valve prosthesis (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:
Multi-centre cross sectional observational study.

Study population:

Patients with valve prostheses identified from the CONCOR national database for adult congenital heart disease .

Main study parameters/endpoints:

Primary outcome measures: VO2max and quality of life.
Secondary outcome measures: prevalence of prosthesis-patient mismatch, incidence of prosthetic valve-related complications.

Study objective

1. Prosthetic valve characteristics (type; location; size resulting in the presence/absence of PPM) are related to functional outcome and quality of life;

2. The incidence/spectrum of prosthetic valve-related complications in adults with CHD differs from populations with acquired valve disease.

Study design

Cross sectional evaluation.

Intervention

N/A

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Adult Congenital Heart Disease patients with a prosthetic heart valve (both homografts, heterografts and mechanical valves in aortic, mitral, pulmonary or tricuspid position) who are included in the CONCOR database and who give informed consent for the study.

Exclusion criteria

Inability to comply with primary endpoint measures (completion of quality of life questionary, VO2max). Pregnant patients will not be included, they may be included > 3 months after pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	600
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1995
NTR-old	NTR2112
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A