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

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21400

Bron
NTR

Verkorte titel
PROSTAVA

Aandoening

Prosthetic Valves; Adult Congenital Heart Disease

Ondersteuning

Primaire sponsor: Netherlands Heart Foundation
University Medical Center Groningen
ICIN
Overige ondersteuning: Netherlands Heart Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. VO2 max;
2. Quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Cross sectional evaluation.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1995
NTR-old	NTR2112

Register	ID
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A