Quality of Life 4: Long-term cardiological and psychosocial outcome in adults operated for congenital heart disease in early childhood: a longitudinal cohort-study of 40-53 years of follow-up.

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This study will focus on the long-term outcome after surgical correction of several congenital heart defects in a non-selected cohort. The repetitive nature of this study will make it possible to analyze specific changes in cardiac function over...

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON48379

Source
ToetsingOnline

Brief title
Quality of Life 4 - QoL4

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Grown-up Congenital Heart disease, patients born with a heart defect

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Subsidie Thorax Foundation ErasmusMC

Intervention

Keyword: Grown-up Congenital Cardiology, Heart surgery, Outcome assesment, Psychological outcome

Outcome measures

Primary outcome

Cardiac outcomes:

1. To describe the life expectancy in patients who underwent corrective surgery

below the age of 15 years because of a congenital heart defect after 40 to 53

years.

Psychological outcomes:

1. To describe the quality of life and psychological functioning in this cohort

and to compare it with a healthy control population.

Secondary outcome

Cardiac outomes:

a. Anamnesis, prevalence of complaints of cardiac failure (NYHA class), rhythm

disorders, daily functioning. Prevalence of cardiovascular risk factors. A

standardized questionnaire will be used.

b. Physical examination (length and weight, bloodpresure, pulse, O2 sat,

auscultation, CVP)

c. Echocardiographic parameters (2D, 3D, PW, CW Doppler, color Doppler, tissue

Doppler, high frame rate)

3. Echocardiographic parameters (2D, 3D, PW en CW Doppler, color Doppler,

tissue Doppler, high frame rate echocardiography)

4. MRI parameters (MRI with contrast)

5. VO2 max

6. ECG parameters

7. Holter (24 hours)

8. Laboratory results (vena punction)

Psychologisch:

1. psychosocial outcome: daily activity, occupational status, sick leave,

career possibilities, application

and benefit of social security, (sexual) relationships, marital status,

offspring.

2. Sexual functioning: erectile function: international index of erectile

function (IIEF), knowledge and fears as to sexual behaviours, anticonception,

pregnancy, delivery, menopause.

3. emotional functioning: psychopathology, self esteem.

4. social functioning

5. health related life styles

6. perception of severity of congenital heart disease.

7. End of life issues

Study description

Background summary

Off al live births around the world, approximately 0.8% is born with a congenital heart defect. In the Netherlands, about 1500 children are born with a congenital heart defect every year. Before surgical therapy for these defects was possible, half children died in their first year of life. Less than 15% reached adulthood.

Thanks to surgical correction, 20 years survival is about 85% nowadays. Approximately 25.000 adults with operated congenital heart disease are alive in the Netherlands right now. However, total correction is rare. Most patients have residual lesions and sequelae. In Rotterdam, surgical correction of congenital heart defects is performed since 1968.

The cohort of patients that was operated between 1968 and 1980 has been studied before in 1990-1991, 2000-2001 and 2011-2012. In some subgroups of patients survival and morbidity were nearly normal, whereas for other subgroups (for example Mustard and Fallot patients) there were worrisome changes in cardiac function and frequent need for re-intervention. Further deterioration of cardiac function can be expected, especially for Mustard patients.

The previous studies also showed psychosocial problems in this cohort of patients. Overall, favorable outcomes on psychosocial functioning and quality of life were found, but also impairments as to educational and occupation levels and physical functioning. Predictors for elevated levels of long-term psychopathology were: being female, restrictions by the scar, low exercise capacity and other physical restrictions. Especially young females were at risk for psychosocial problems (e.g. anxieties as to sexuality, pregnancy, delivery).
Based on these previous findings, an increase in psychosocial problems can be expected when these patients get older. Accurate information about long term follow up is therefore very important for treatment and prognosis of these patients.

The current study proposal makes it possible to describe the natural and unnatural history in this specific cohort of patients in the very long term. Specific information will be acquired about the problems patients are confronted with in this period of their life, when they are growing older.

Study objective

This study will focus on the long-term outcome after surgical correction of several congenital heart defects in a non-selected cohort. The repetitive nature of this study will make it possible to analyze specific changes in cardiac function over time.
Furthermore, the impact of a congenital heart defect on several psychological

variables and quality of life will be investigated.

The main goal of this project will be to obtain objective information about mortality, morbidity and cardiac function and also about quality of life and psychological functioning in a cohort of patients, who underwent surgical correction of congenital heart disease at young age, specifically ASD, VSD, tetralogy of Fallot, transposition of the great arteries and pulmonary stenosis.

Study design

Single center, longitudinal cohort study of survival, morbidity and quality of life in patients who underwent surgical correction of a congenital heart defect in childhood before the age of 15 in Rotterdam, between 1968 and 1980. Included are patients who underwent correction of an ASD, VSD, pulmonary stenosis, tetralogy of Fallot and transposition of the great arteries. This cohort was also studied between 1990-1991, 2000-2001 and 2011-2012.
All patients will be invited to our outpatient clinic of the department of cardiology of the Erasmus Medical Center. This study will be conducted between January 2020 and December 2021.

All patients will undergo extensive outpatient check-up, including medical history taking, physical examination, ECG, blood testing, exercise testing, echocardiography, holter examination, cardiac MRI or cardiact CT. Psychological examination exists of computing
psychological questionnaires and a semi-structured interview. Testing wil be done in one visit as far as possible, to minimise
patient burden. Results will be stored in a database and compared with the results in the same patients of the prior studies.

Study burden and risks

Due to the non-invasive nature of the research, the health risks are very low. In those cases where a cardiac MRI will be
performed, use of contrast is sometimes needed. In rare cases a patient is allergic to the contrast agent used. Patients will be
asked specifically if they have had allergic reactions before. Special care will be available at all times to prevent and treat an
allergic reaction (by antihistaminic and corticosteroids). The same approach will be followed in case there is a contra-indication or MRI and a dynamic CT will be performed.

For venapunction, standard precautions will be taken. For patients, taking part in this study will mean that a they will spend about 7,5 hours in total in the outpatient clinic, undergoing both medical and psychological tests. Most of the studies performed will be the same as patients

would undergo in their routine visit.

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

Patients who underwent cardiac surgery in Rotterdam between 1968 and 1980 becuase of atrial septum defect, ventricular septal defect, tetralogy of Fallot, transposition of the great arteries and pulmonary stenosis. At the moment of surgery they were 15 years or younger. Singned informed conseent.

Exclusion criteria

Patients who were older then 15 years at the moment of surgery
Patients who received a palliative shunt
No informed consent
Patients who do not speak the Dutch language
Patients who have renal insufficiency (eGF<30ml/min) for gadolinium contrast in the cardiac MRI or cardiac CT.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	342
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-11-2019
Application type:	First submission
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	NL68281.078.18