Long term Results Congenital Cardiologic Abnormalities (LUCCA).

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22025

Source
NTR

Brief title
LUCCA

Health condition

congenital, heart-surgery, follow-up, quality of life.
congenitaal, hartchirurgie, follow-up, kwaliteit van leven.

Sponsors and support

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Intervention

Outcome measures

Primary outcome

Mortality, morbidity (defined as re-operation, re-intervention, pacemaker implantation, arrhythmias and cardiac failure).

Secondary outcome

Heart function of the left and right ventricle, exercise capacity and quality of life.

Study description

Background summary

Background:

A congenital cardiologic abnormality is encountered 8 per 1000 live births. In the present era the 20 years survival of patients born with a congenital heart defect is 85 percent or more. Since 1968 surgical correction of these defects can be preformed in Rotterdam using a hart-long machine.
Complications and residual lesions seen after the operation of congenital heart abnormalities are valve dysfunction, arrhythmias, endocarditis and heart failure. By registrating these problems, there will be a better understanding of the late problems and a better insight will be gained in what topics need special attention and what is the best timing for (re-) intervention.
Long-term follow-up of congenital heart disease patients is important to get insight in survival as well as quality of life. Whether with the contemporary surgical techniques and psychological help, the patients have a good quality of life, is one of the questions to be answered. In the present study we want to investigate the cohort of patients operated on between 1980 and 1990 and compare the results with a cohort study of patients operated between 1968 and 1980.

Objective:

To get insight in the long term results (mortality, morbidity and cardiologic function) of patients with congenital heart disease operated at young age. To compare whether the changes in surgical techniques have resulted in an increase of (complication free) survival and quality of life.

Design:

This study is a clinical longitudinal cohort study.

Population:

The following patient groups with a congenital heart disease operated on in the Erasmus MC in the period 1980 till 1990, younger then 15 at operation: atrial septum defect (ASD), tetralogy of Fallot, transposition of the great arteries and a complex heart disease.

Primary parameters/outcome:

Primary end points are mortality, morbidity (defined as re-operation, re-intervention, pacemaker implantation, arrhythmias and cardiac failure).

Secondary parameters:

Heart function of the left and right ventricle, exercise capacity and quality of life.

Risks:

Due to the non-invasive nature of the research (ECG, holter, echocardiography and bicycle exercise test) the health risks are very low. In most cases also an MRI will be made. In very rare cases a patient is allergic to the contrast agent used at MRI. Patients will be asked whether they are allergic. Special care will be available at all time in case of an allergic reaction.

Study objective

To get insight in the long term results (mortality, morbidity and cardiologic function) of patients with congenital heart disease operated at young age. To compare whether the changes in surgical techniques have resulted in an increase of (complication free) survival and quality of life.

Study design

One visit, circa 19-29 year after the first operation.

Intervention

This study is a clinical longitudinal cohort study. Interventions: ECG 12 lead, 24 hour holter, bicycle exertion test, TTE, Physical examination, Psychological investigation, MRI.

Contacts

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Eligibility criteria

Inclusion criteria

The following patient group with a congenital heart disease operated on in the Erasmus MC in the period 1980 till 1990, younger then 15 at operation:

atrial septum defect (ASD), tetralogy of Fallot, transposition of the great arteries and a complex heart disease.

Exclusion criteria

Non compos mentis, mentally disabled persons.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	280
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	NL1540
NTR-old	NTR1611
Other	: THCHOZ 2008-12
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results