Long term Results Congenital Cardiologic Abnormalities (LUCCA).

Gepubliceerd: 02-01-2009 Laatst bijgewerkt: 13-12-2022

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 (…

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22025

Bron
NTR

Verkorte titel
LUCCA

Aandoening

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

Ondersteuning

Primaire sponsor: Dr. J.W. Roos-Hesselink, cardioloog
Erasmus MC Rotterdam
's Gravendijkwal 230
3015 CE Rotterdam
Afdeling Cardiologie
Email: j.roos@erasmusmc.nl
Tel: 010-7032432
Overige ondersteuning: Dr. J.W. Roos-Hesselink, cardioloog
Erasmus MC Rotterdam
's Gravendijkwal 230
3015 CE Rotterdam

Afdeling Cardiologie
Email: j.roos@erasmusmc.nl
Tel: 010-7032432

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Erasmus MC Rotterdam
's Gravendijkwal 230
P.T.E. Ruys
Afd. cardiologie/thoraxchirurgie
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7033989

Wetenschappelijk

Erasmus MC Rotterdam
's Gravendijkwal 230
P.T.E. Ruys
Afd. cardiologie/thoraxchirurgie
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7033989

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Non compos mentis, mentally disabled persons.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	280
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	NL1540
NTR-old	NTR1611
Ander register	: THCHOZ 2008-12
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten