Physical fitness and daily activities of children with congenital heart disease.

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- To determine physical fitness in children with a congenital heart disease (ventricular septum defect, atrium septum defect, tetralogy of Fallot, transposition of large arteries and patients after a (modified) Fontan-operation) and to compare...

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

Summary

ID

NL-OMON30800

Source
ToetsingOnline

Brief title
Physical fitness in children with congenital heart disease

Condition

- Congenital cardiac disorders

Synonym
congenital heart disease, heart disease in children

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Stichting de Nijmeegse 4-daagse

Intervention

Keyword: children, congenital heart disease, daily activities, physical fitness

Outcome measures

Primary outcome

Physical fitness, examined during the incremental cycling test. In addition, activity patterns of the children for a period of 7 days will be registered using an activity monitor. Using these data, insight is provided into the background of the possible differences in physical fitness and physical characteristics between the several congenital heart diseases and between congenital heart disease and controls.

Secondary outcome

Physical characteristics (i.e., fat percentage, body mass index, pulmonary function) will be examined using non-invasive and not painful/harmful procedures/techniques.

Study description

Background summary

The prevalence of congenital heart disease is ~38500 in the Netherlands alone. Due to the improved quality of the treatment of congenital heart diseases and a relatively low mortality rate, an increase in the prevalence of children and adults with congenital heart diseases is present. The beneficial health effects of physical exercise in children are frequently described. However, because of *over-protection* and (primary or secondary) an attenuated physical capacity in children with congenital heart disease, most of these subjects have a sedentary life style. An importance consequence of this sedentary life style is the marked increased risk to develop chronic diseases associated with physical inactivity and attenuated quality of life.
Previous studies demonstrated that inactive children are more likely to remain inactive at the adult or adolescence age. This emphasizes the importance of

promotion of an active life style, preferably at an early age. The physical fitness level can be determined through the use of exercise tests, which can be utilized to determine a safe range in which these subjects can be physically active. Determining physical fitness level can help to match the level of physical activity in daily living, sports activities and therapy with the physical fitness of these subjects. This will eventually lead to an improvement in the quality of life. However, to date only few studies examined the level of physical fitness and daily activities in children with congenital heart disease.

Study objective

- To determine physical fitness in children with a congenital heart disease (ventricular septum defect, atrium septum defect, tetralogy of Fallot, transposition of large arteries and patients after a (modified) Fontan-operation) and to compare physical fitness between these groups.
- Compare physical fitness in children with a congenital heart disease (all 5 subdivision) with age-matched healthy children.
- To determine the daily activity pattern of children with a congenital heart disease (all 5 subdivisions) and healthy age-matched children.
- Determine anthropometrical characteristics of children with a congenital heart disease (all 5 subdivisions) and healthy age-matched children.

Study design

On Day 1, physical fitness and anthropometrical characteristics will be examined. Subsequently, the children receive an apparatus that registers the activities performed throughout the day. The children will be instructed to wear with apparatus during the day for a period of 7 days. After these 7 days, the children report to the laboratory to return the apparatus. In addition, a second cycling test is performed to examine the physical fitness level in these children. These results will be compared with an age-matched group of healthy children and between the 5 included groups of congenital heart disease.

Study burden and risks

The single test that may be related to an increased risk is the incremental (symptom limited) maximal cycling test. Since early *90-ties, this test is performed on a regular basis as a standard procedure at the Department of Pediatrics in children with a congenital heart disease. As such, the test will be performed according to the standard experimental protocol as used at the Department of pediatrics and by several other researchers in the past in this group of children. Each test will be performed under continuous supervision of a physician. During the test, heart rate, oxygen consumption, ventilation, blood pressure and saturation will be registered continuously. This enables the researcher(s) and physician(s) to evaluate the most important vital functions

to provide an accurate view of the clinical and physiological condition of the child during performance of the test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- aged between 8 and 17 years
- congenital cardiac disease (ventricular septum defect (VSD), atrium septum defect (ASD), Tetralogy of Fallot (TF), transposition large arteries (TLA), patients after the (modified) Fontan-operation)
- signed informed consent

Exclusion criteria

- exept the congenital heart disease, no other pathologies
- metabolic, neurologic, muscular of orthopedic pathology/malformation
- syndromes in which congenital heart disease is only 1 of the symptoms
- decompensatio cordis (NYHA-class I-IV)
- cyanosis (baseline saturation <90%)
- tachycardia/bradycardia
- acute illness/disease (such as viral infections)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL16342.091.07