Are children with congenital heart or lung disease fit-to-fly?

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

Summary

ID

NL-OMON42079

Source
ToetsingOnline

Brief title
Fit-to-Fly study / F2F-study

Condition

- Congenital cardiac disorders
- Congenital respiratory tract disorders

Synonym
Congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: airtravel, altitude, hypoxia, oxygen saturation

Outcome measures

Primary outcome

The primary aim of this study is to investigate the feasibility of a hypoxic challange test (HCT) in children with congenital heart of lung disease. This HCT was previously developped and use in healthy children (Kobbernagel et al 2013). Feasibility is defined as succesful run through of the measurements in 75% of the subjects.

Secondary outcome

The secondary aim is to monitor the oxygen saturation during each of the activities using a pulse oxymeter (index finger) and a tissue saturation monitor (NIRS) on the forehead and leg. (m. vasus lateratus). These values will be compared to the values obtained breating regular (sea level) air (21% oxygen).

Study description

Background summary

Children with a congenital heart and lung disease have a reduced function of the oxygen transport system from lung to muscle and organs. During a stay at altitude or during an airline flight, the barometric pressure is reduced and hence the partial pressure for oxygen. This could further impde the functioning of the oxygen transport system.

Study objective

This study will investigate the feasibility of a hypoxic challaenge test (60 minutes duration). During this test the inspired air will have a oxygen content

of 15%. This is a comparable value as is used during a commercial airline flight (ca 2500 meter, oxygen % 15%). Furthermore, we will investigate the oxygen saturation as well as the tissue saturation in blood and muscle of the subjects.

Study design

This is an observational pilot study with non-invasive measurements.

Subjects will be equipped with a face mask. This mask will be connected to a altitude simulator (Hypoxico Hypoxic generator) dat will simulate an altitude of 2500 meter. The simulator generates air with an oxygen content of 15%.
A pulse oxygen saturation meter will be attached to in index finger of a subject, and a NIRS probe will be attached to the forehead and leg.
The measurements will be performed during a standardized hypoxic challange test (HCT). The HCT consists of alternating, non-randomised periods of breathing room air (10 minutes) followed by a period at a simulated altitude of 2500 above sea level. During this period the patients will be monitored, while sitting and watching a DVD (15 min), laying supine (10 min) and standing (5 min) and while walking on a treadmill at 3 km/h (5 min) and at 5 km/h (5 min).

All measurements will be performed at the Child Development & Exercise Center by an exercise physiologist of the Wilhelmina Children's Hospital.

Study burden and risks

The burden and risks are estimated to be minimal.

Grouprelatedness: Children have a unique physiological response to exercise, which develops with growth and developments. This response is differnt compared to adults. In addition, exercise responses (ventilation and circulation) are different in children with heart or lung disease compared to healthy children. Therefore, this study can only be conducted in this patient population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Children with congenital heart or lung diseae
Age between 8 and 21 years of age
Able to walk (walking on treadmill)

Exclusion criteria

Lungfunction (FEV1) below 70% of predicted or oxygen saturation in rest <90%.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2015
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	30-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-08-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL50104.041.14