The hemodynamic and pulmonary effects of acute high altitude exposure at rest and during exercise in patients with complex congenital heart diseases

Published: 09-08-2016 Last updated: 20-04-2024

The primary aim of this study is to study the hemodynamic and pulmonary effects of acute altitude exposure in rest and during exercise in children and adults with complex congenital heart disease. We will compare theire reponses with gender and age...

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

Summary

ID

NL-OMON46314

Source ToetsingOnline

Brief title HYPOXIA study

Condition

Congenital cardiac disorders

Synonym congenital heart disease

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: altitude, exercuise physiology, hypoxia, saturation

Outcome measures

Primary outcome

The hemodynamic and pulmonary effects of acute high altitude exposure. Blood

pressure, heart rate, exercise capacity, saturation, cardiac output, peak O2

uptake en ventilation will be monitored.

Secondary outcome

The association between desaturation and decrease in exercise capacity will be

studied as a secondary objective.

Study description

Background summary

Patients with a congenital heart 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 impede the functioning of the oxygen transport system because of their limited reserve capacity.

Study objective

The primary aim of this study is to study the hemodynamic and pulmonary effects of acute altitude exposure in rest and during exercise in children and adults with complex congenital heart disease. We will compare theire reponses with gender and age matched apparently healthy peers.

It is our hypothesis that children do have a different response compared to adults and that patients with congenital heart disease will differ from healthy peers.

Our secondary objective is to study the association between desaturation and

decrease in exercise capacity.

Study design

This is an explorative observational study with non-invasive measurements. Testing will be performed at the Wilhelmina Children*s Hospital; including, cardiopulmonary exercise stress testing on a cycle ergometer (duration 10-15 minutes). A second comparable test will be perfomed (maximal 3 months later), at a simulated altitude of 2500 meter. Differences between sealevel and 2500 meter (children vs. adults and healthy vs cong. heart disease) will be investigated

Study burden and risks

Risk and burden are minimal.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Children and adults with complex congenital heart disease between 8 years and 40 years of age and apparently helathy peers are eligible.

Exclusion criteria

* Unstable cardiac function (hemodynamic instable irregular heart rate and blood pressure)
* Fever

* Mental or physical disabled patients not able to perform an exercise stress test on a cycle ergometer

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2016
Enrollment:	60
Туре:	Actual

Ethics review

Approved WMO	
Date:	09-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	02 11 2016
Date.	02-11-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	25-10-2017
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 CCMO **ID** NL56769.041.16