The effect of N-acetylcysteine and ascorbic acid on pulmonary arterial pressure and ventilation during normoxia, hypoxia and hyperoxia and total oxidant capacity.

Published: 15-07-2009
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In this study we will therefore investigate the influence of hypoxia and anti oxidants on HVR and HPV.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON33919

Source
ToetsingOnline

Brief title
PAPOX

Condition

- Pulmonary vascular disorders

Synonym
acute mountain sickness, COPD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anti-oxidant, hypoxic pulmonay vasoconstriction (HPV), hypoxic ventilatory respons (HVR), oxidant capacity

Outcome measures

Primary outcome

pulmonal arterial pressure

total oxidant capacity

The ventilation will be analyzed on-line and is visible on-screen using custom

made software (ACQ and RESREG developed by Erik Olofsen and Erik Kruyt,

respectively). The breathing data will be collected on disc on a

breath-to-breath basis for further analysis.zie protocol pagina 6 data steering

Secondary outcome

none

Study description

Background summary

The background mechanism of the oxygen sensing in the human body still remains to be elucidated. One of the proposed mechanisms is through the mitochondrial reactive oxygen species hypothesis. This hypothesis states that tissue hypoxia generates ROS. These ROS then would influence the ventilatory respons through the carotid bodies and the reactivity of the pulmonary arterial smooth muscle cells.

Study objective

In this study we will therefore investigate the influence of hypoxia and anti

oxidants on HVR and HPV.

Study design

double blind placebo controlled trial
three following sessions:
1. placebo
2. ascobid acid
3. acetylcystein

Intervention

arterial line,
venous line
hyperoxia
hypoxia

Study burden and risks

The strain for the volunteers considering the study medications is nausea and vomiting when taken in high dosages. The dosages durng this investigation will be much lower.
Hypoxia might cause a headache, which will be treated with paracetamol.
The venous and arterial lines might cause a haematoma, which will disappear by itself. Arterial lines are related with clothing, but only when more than 36 hours in situ. During this investigation the arterial line will be no longer in situ than 4 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

That the volunteer is healthy

Exclusion criteria

Exclusion criteria are:
• Obesity (BMI > 30)
• Presence of medical disease: heart-, lung-, liver-, kidney- and lung disease; diabetes
• Presence of psychiatric disease
• History of chronic alcohol or drug use
• Possibility of pregnancy
• Lactation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	acetylcystein
Generic name:	n-acetylcystein
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	vitamin C
Generic name:	ascobid acid
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	15-07-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2008-008453-29-NL
CCMO	NL26258.058.09