

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

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In this study we will therefore investigate the influence of hypoxia and anti oxidants on HVR and HPV.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Pulmonary vascular disorders
<b>Study type</b>	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. ascorbic acid
3. acetylcysteine

## **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 during 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**

### **Public**

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### **Scientific**

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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

EudraCT

CCMO

### ID

EUCTR2008-008453-29-NL

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