

# Measuring cognitive functioning during hypoxia with near infrared spectroscopy and electro encephalography

Published: 11-02-2009

Last updated: 05-05-2024

The main objective of this study is to determine the relationship between cognitive functioning and the NIRS/ EEG signal under hypoxic circumstances.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33270

### Source

ToetsingOnline

### Brief title

Cognitive functioning and hypoxia

### Condition

- Other condition

### Synonym

hypoxia, insufficient oxygen

### Health condition

functioneren onder hypoxie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** TNO

**Source(s) of monetary or material Support:** Centrum voor Mens en Luchtvaart

## Intervention

**Keyword:** Cognitive functioning, hypoxia, NIRS: EEG

## Outcome measures

### Primary outcome

The main study parameters are cognitive functioning (working memory, tracking, vigilance, planning), blood oxygen saturation levels (cerebral), brain activity of the frontal cortex, heart rate and blood pressure.

### Secondary outcome

peripheral oxygen saturation levels, heart rate and blood pressure.

## Study description

### Background summary

Previous research has shown that mild to moderate hypoxia (90-75%) decreases human performance by impairing physiological and cognitive functioning. It is important to investigate these effects because various complex tasks are performed at mild to moderate levels of hypoxia (e.g. pilots, people working at altitude). Cognitive functioning might be altered by the impaired cerebral oxygen saturation in the blood. Near infrared spectroscopy can be used to assess this cerebral oxygen saturation. Simultaneously assessing the electro-encephalograph at the same positions on the cortex can be of an added value. The purpose of this study is to measure how cognitive functioning is affected by mild to moderate hypoxia and to determine if these effects are reflected in NIRS and EEG brain signals. Especially of interest is the cerebral oxygen saturation of the frontal cortex.

### Study objective

The main objective of this study is to determine the relationship between

cognitive functioning and the NIRS/ EEG signal under hypoxic circumstances.

## **Study design**

This study has a single blind design. The conditions of mild and moderate hypoxia and the order of the tasks will be balanced across subjects

## **Intervention**

Partly deoxygenated air will be inhaled by the subjects with a special breathing mask. Oxygen saturation levels will be manipulated and actively kept constant at (1) 98%, baseline sea level, (2) 90%, as found in subjects residing at an altitude of approximately 2500-3500m and (3) 80%, as found in subjects residing at an altitude of approximately 4000-5000m. Oxygen saturation will be measured in the frontal cortex and peripherally. The oxygen saturation level of the frontal cortex will be assessed with near-infrared spectroscopy (NIRS). Peripherally, oxygen saturation will be measured at the ear using a pulse oximeter. During each of the three saturation levels, subjects will perform three different cognitive tasks (N-back, tower of Hanoi and VigTrack). To assess the activity of the frontal cortex electro-encephalography (EEG) measurements will be done simultaneously.

## **Study burden and risks**

Before the study, subjects will be screened, based on their medical history, to ascertain their health. After inclusion the subjects will be administered to the mild and moderate hypoxia levels. The subjects are instructed that hypoxia will induce deep breathing and an increase of heart rate, and that these symptoms should be interpreted as physiologically normal. Other symptoms as nausea, dizziness, temporarily reduced vision, hyperventilation and syncope (fainting) are more severe and are an indication of acute hypoxia. In case symptoms as mentioned above appear, the experiment will be ended immediately. The mild and moderate levels of hypoxia are sufficient to expect an impaired cognitive functioning due to the lower oxygen saturation both peripherally and cerebrally.

## **Contacts**

### **Public**

TNO

kampweg 5  
3769 DE Soesterberg  
Nederland

**Scientific**  
TNO

kampweg 5  
3769 DE Soesterberg  
Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

1. Non smoking, or stopped at least 1 years ago.
2. Aged between 18 and 30 years, at day 01 of the study.
3. Apparently healthy based on the anamnesis (see appendix).
4. Having given their written informed consent.
5. Willing to comply with the study procedures.
6. Willing to accept use of all anonymous data, including publication, and the confidential use and storage of all data.
7. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

### **Exclusion criteria**

1. Medical problems (amongst others, cardiovascular and respiratory diseases).
2. No use of prescribed medication in the last 14 days prior to start of the study, with the exception of the use of aspirins and ibuprofen and oral contraceptives (o.a.c.). These can be taken until 72 hours prior to the start (this does not apply for o.a.c.) .
3. Use of drugs.
4. Sickness in the last 7 days prior to the start of the study.
5. Not willing to except the transfer of relevant study results to their physician.
6. Having donated blood in the last 14 days

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2009
Enrollment:	18
Type:	Actual

## Ethics review

Approved WMO	
Date:	11-02-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

## 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	NL26501.028.09