# Exhaled Breath Profile at altitude

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON26964

**Source**
NTR

**Brief title**
EBP at altitude

**Health condition**

Acute Mountain Sickness (AMS), High Altitude Cerebral Edema (HACE) and High Altitude Pulmonary Edema (HAPE).

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center
**Source(s) of monetary or material Support:** Nederlandse Klim- en Bergsportvereniging
Institute of Sport Science, Faculty of Biology and Medicine, University of Lausanne

### Intervention

### Outcome measures

**Primary outcome**

AMS breathprint generating study: a specific VOC breathprint of subjects with AMS, measured during a stay in the Capanna Regina Margherita, Italy, at an altitude of 4559 meter.

Proof of concept study: A VOC breathprint of subjects with, or without AMS, measured during a stay in the Capanna Regina Margherita, Italy, at an altitude of 4559 meter.

### Secondary outcome

Specific VOC breathprint which is associated with the development of HACE, as measured during a stay in the Capanna Regina Margherita, Italy, at an altitude of 4559 meter.
Specific VOC breathprint which is associated with the development of HAPE, as measured during a stay in the Capanna Regina Margherita, Italy, at an altitude of 4559 meter.

SGVAS score that is associated with AMS diagnosis (scored by LLSRS and the ESQc).
SGVAS score that is associated with specific AMS VOCs breathprints.

− Clinical measurements that are associated with AMS.

− IGVAS score that is associated with AMS diagnosis (scored by LLSRS and the ESQc).

## Study description

### Background summary

The proposed study will assess the ability to discriminate between breathprints of healthy controls and subjects diagnosed with AMS, HACE or HAPE. We further will explore the usefulness of VAS for AMS by completing subject self assessment by expert physician AMS scoring.

Subjects visiting the Capanna Regina Margherita (Italy) are recruited. These subjects are from different nationalities (for example Italian, French, Swiss, Austrian, German, Dutch, English, Spanish)

### Study objective

There is no reliable biological marker for the diagnosis of Acute Mountain Sickness (AMS), so AMS is presently assessed with questionnaires: the Lake Louise self-report score (LLSRS) and the abbreviated Environmental Symptoms Questionnaire (ESQc). Recently Visual Analogue Scales (VAS) have been introduced to quantify AMS symptom intensity.
In the present study, we propose measurements of volatile organic compounds (VOCs) in exhaled air to provide a non-invasive and objective test for diagnosing AMS, High Altitude Cerebral Edema (HACE) and High Altitude Pulmonary Edema (HAPE). VOCs can be measured with electronic nose (eNose) technology, which forms a breathprint of the different VOCs. The proposed study will assess the ability to discriminate between breathprints of healthy controls and subjects diagnosed with AMS, HACE or HAPE. We further will explore the usefulness of VAS for AMS by completing subject self assessment by expert physician AMS scoring.

**Study design**

All tests will be performed on a single occasion on each subject participating in the study.

**Intervention**

N/A

# Contacts

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# Eligibility criteria

## Inclusion criteria

All subjects visiting the Capanna Regina Margherita (4554 m, Italy) willing and able to comply with the study protocol.

## Exclusion criteria

1. Use of inhalation steroids.

2. Use of inhalation beta-adrenergic agonists.

3. Use of acetazolamide.

4. A course of oral corticosteroids, antibiotics or a respiratory infection within 4 weeks prior to

the study.

5. LLS ≤ 3 of ESQc ≤ 0,7

6. Age < 18 years

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Factorial |
| Allocation: | Non controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2013 |
| Enrollment: | 140 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 09-07-2013 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL3876 |
| NTR-old | NTR4073 |
| CCMO | NL44930.058.13 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A