

# Heat-exchanger breathing masks during heavy exertion in cold conditions; protection or a hindrance?

<b>Submission date</b> 27/02/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/11/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Physical activity in sub-zero temperatures may induce bronchial obstruction in healthy subjects. Cold-weather endurance athletes, such as cross-country skiers, have an increased prevalence of asthma. Little is known about whether breathing masks prevent airway damage in winter endurance athletes. The aim is to investigate the effect of breathing mask usage during intense physical exercise in cold air on markers of airway damage as well as physiological and perceptual responses to exercise in the cold.

### Who can participate?

Well-trained adults with experience of treadmill-running, without asthma, allergy, or breathing problems.

### What does the study involve?

The exposures will take place in -15 °C on two separate occasions at least 48 hours apart. Throughout one of the two exposures, study subjects will use a heat-exchanging breathing mask. Each exposure will last 45 minutes and consist of an exercise protocol to simulate a prolonged warm-up and 4 minutes long "distance-trial" of running. Symptoms will be reported immediately pre, during, and immediately after exiting the chamber. Dynamic spirometry and impulse oscillometry will be conducted before and immediately after each exposure. Participants will provide blood and urine samples pre and 60 minutes post-exposure for analysis of biochemical markers of airway damage. Performance will be evaluated as the distance achieved during 4 minutes of running.

### What are the possible benefits and risks of participating?

We assume the exposures and associated exercise protocol will induce acute symptoms such as fatigue, dyspnea, rhinitis, and cough that will resolve within 15 minutes after exiting the chamber. We do not expect tissue injury or frostbite to occur. Venepuncture will induce local pain. Spirometry requires 3-8 forced expiratory manoeuvres which may feel strenuous. We do not expect that exposures nor the measurements will cause any long-term harm for the participants.

Where is the study run from?

1. The Swedish Winter Sports Research Centre, Mid Sweden University, Östersund, Sweden
2. Public Health and Clinical Medicine Umeå University, Umeå, Sweden

When is the study starting and how long is it expected to run for?

January to June 2019

Who is funding the study?

1. The siblings Persson's fund, Region Jämtland Härjedalen
2. Unit of Research, Education and Development, Region Jämtland Härjedalen
3. Gunhild and Assar Carlsson's fund, Region Jämtland Härjedalen
4. Rolf och Gunilla Enström's foundation for research and development (Östersund, 2022)
5. Mid Sweden University and Östersund City Council financial agreement (2022)

Who is the main contact?

Nikolai Stenfors, [nikolai.stenfors@umu.se](mailto:nikolai.stenfors@umu.se)

## Contact information

### Type(s)

Public

### Contact name

Mr Nikolai Stenfors

### ORCID ID

<https://orcid.org/0000-0002-1684-1301>

### Contact details

Kyrkgatan 16

Östersund

Sweden

83131

+46 63153000

[nikolai.stenfors@umu.se](mailto:nikolai.stenfors@umu.se)

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Version 1 (2018-11-02)

## Study information

## Scientific Title

In healthy subjects, do heat and moisture exchange mask attenuate airway effects of physical activity in subzero temperature?

## Acronym

AEGIS3

## Study objectives

What is the effect of use versus non-use of a heat-moisture exchanging breathing mask (HME) during moderate to severe-intensity exercise in the cold with regard to; respiratory function, biomarkers of airway damage, respiratory symptoms, heart rate, breathing rate, muscle oxygenation, perceived exertion during exercise, and exercise performance?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 20/12/2018, Regional Ethical Review Board at Umeå University (Regionala etikprövningsnämnden, Samverkanshuset, Universitetsområdet, 901 87 Umeå; epn@adm.umu.se; +4690 7867254), ref: 2018-419-31M

## Study design

2x2 cross-over study

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Airway injury

## Interventions

Current interventions as of 20/06/2019:

All participants will complete two standardized 45-minutes exercises in an environmental chamber with a temperature of - 15 degrees Celsius, one exercise with a HME and one without HME.

The exercise protocol will simulate a prolonged warm-up and 4 minutes long "distance-trial" of running.

1. Chamber environment: automatic digital logging
2. Symptoms: self-reported written questionnaires
3. Spirometry: digital
4. Biochemical markers: Manual export of data from paper sheets with results into digital files.
5. Heart rate, breathing rate, muscle oxygenation, performance: Manual data collection, export into digital files

Previous interventions:

All participants will complete two standardized 45-minutes exercises in an environmental chamber with a temperature of - 15 degrees Celsius, one exercise with a HME and one without HME.

The exercise protocol will simulate a prolonged warm-up and sprint-ski competition.

1. Chamber environment: automatic digital logging
2. Symptoms: self-reported written questionnaires
3. Spirometry: digital
4. Biochemical markers: Manual export of data from paper sheets with results into digital files
5. Pexa: Manual export of data from paper sheets with results into digital files
6. Heart rate, breathing rate, muscle oxygenation, performance: Manual data collection, export into digital files

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Not provided at time of registration

### **Primary outcome(s)**

Delta-FEV1 (forced expiratory volume first second), measured by dynamic spirometry. Delta-FEV1 is FEV1 immediately post exposure minus FEV1 pre exposure. Delta-FEV1 with HME compared to delta-FEV1 without HME.

### **Key secondary outcome(s)**

Current secondary outcome measures as of 01/11/2024:

1. Delta airway resistance (immediately post - pre exposure) using impulse oscillometry
2. Airway symptoms using questionnaires, pre, during, and post exposures
3. Biochemical markers of airway damage (CC-16 and interleukins, not yet specified) measured in blood samples pre and 60 minutes post exposures
4. Urine CC-16 measured pre and 60 minutes post exposures
5. Heart rate and breathing rate measured during exposures
6. Muscle oxygenation measured during exposures using (MOXY muscle oxygen monitor, Fortiori design LLC, Minnesota, USA)
7. Performance will be defined as distance covered by a 4 minutes long sprint of running
8. Urinary LTE<sub>4</sub> and 11β-PGF<sub>2α</sub> pre and 60 min post exposure

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Previous secondary outcome measures:

1. Delta airway resistance (immediately post - pre exposure) using impulse oscillometry
2. Airway symptoms using questionnaires, pre, during, and post exposures
3. Biochemical markers of airway damage (CC-16, 8-isoprostane, IL-1 $\beta$ , IL-6, and TNF- $\alpha$ ) measured in blood samples pre and 60 minutes post exposures
4. Urine CC-16 measured pre and 60 minutes post exposures
5. Particles in exhaled breath using PExA instrument, pre and immediately post exposures
6. Heart rate and breathing rate measured during exposures
7. Muscle oxygenation measured during exposures using (MOXY muscle oxygen monitor, Fortiori design LLC, Minnesota, USA)
8. Performance will be defined as the time taken to complete the TT

**Completion date**

30/06/2019

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 20/06/2019:

1. Healthy, well-trained adults
2. Experience of treadmill running

Previous inclusion criteria:

1. Healthy, competitive cross-country skier
2. > 3 years training experience and should be experienced in treadmill roller-skiing using the classical diagonal stride technique

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

23

**Key exclusion criteria**

1. No reported airway infection within 4 weeks prior to each visit
2. Asthma, lung diseases and other diseases that may significantly affect their physical performance status

**Date of first enrolment**

01/01/2019

**Date of final enrolment**

31/05/2019

## **Locations**

**Countries of recruitment**

Sweden

**Study participating centre**

**The Swedish Winter Sports Research Centre, Mid Sweden University**

Studentplan 4

Östersund

Sweden

831 40

**Study participating centre**

**Public Health and Clinical Medicine Umeå University**

Umeå

Sweden

901 87

## **Sponsor information**

**Organisation**

Mid Sweden University

**ROR**

<https://ror.org/019k1pd13>

**Organisation**

Public Health and Clinical Medicine Umeå University

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

The siblings Persson's fund, Region Jämtland Härjedalen

**Funder Name**

Unit of Research, Education and Development, Region Jämtland Härjedalen

**Funder Name**

Gunhild and Assar Carlsson's fund, Region Jämtland Härjedalen

**Funder Name**

Rolf och Gunilla Enström's foundation for research and development (Östersund, 2022)

**Funder Name**

Mid Sweden University and Östersund City Council financial agreement (2022)

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		29/03/2021	17/08/2022	Yes	No
<a href="#">Results article</a>		07/04/2022	17/08/2022	Yes	No