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# Does session duration affect lung function during exercise in the cold?

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 31/01/2022 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 01/02/2022 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 16/05/2022 | Respiratory | |

## Plain English summary of protocol

Background and study aims
Studies have shown that training in the cold can have harmful effects on the airways. The lungs must warm and function the cold, dry air and this process can lead to short-term and reversible narrowing of the airways, inflammation, and the onset of respiratory symptoms. However, it is currently unknown to what extent different training factors, such as the duration of training sessions, can cause damage to the airways, which puts athletes at risk of developing asthma or respiratory symptoms.
The overall purpose of the study is therefore to investigate how two different training sessions performed in a cold, dry environment, with the same intensity but different duration, affect respiratory health.

Who can participate?
Healthy adults aged 18-45 years, training for endurance sports for at least 3 h per week and including regular sessions lasting more than 90 minutes.

What does the study involve?
Participants will run in an environmental chamber at -15 °C on two occasions. Before and after each running trial, we will measure several biochemical markers (from blood and breath samples) that represent immune function and injury to the airway lining, test participants' lung function and ask participants to report any respiratory symptoms that arise. On a separate occasion, participants will also perform a maximum oxygen uptake capacity test to provide preliminary information about their physical fitness.

What are the possible benefits and risks of participating?
A potential risk is that prolonged exercise can cause a short-term reduction of the activation or efficacy of the immune system for a few hours after the workout. For this reason and in view of the ongoing COVID-19 pandemic, we will participants routinely train for similar durations in similar environments. We also recommend that participants rest for 24 hours after the 90-min session in the lab, and follow all guidelines from the Swedish Public Health Agency. In addition, only 2-3 people will be in the lab during the test days and we will make sure none of them have symptoms.

The maximal exercise test may cause mild fatigue and soreness in the muscles but it is a natural, short-lived response that usually passes within a few days. To minimize any muscle damage during the test, participants will perform a standardised warm-up. Also during the treadmill tests, participants will be secured with a harness attached to an automatic stop that is activated in the event of a fall.

Where is the study run from?
Data collection takes place at the Swedish Winter Sports Research Centre, Östersund, Sweden; part of Mid Sweden University.

When is the study starting and how long is it expected to run for?
September 2020 to March 2021

Who is funding the study?
This study received partial funding from Östersund Municipality as part of the project "Athletes' health as an underlying factor for performance" (Sweden)

Who is the main contact?
Dr Helen Hanstock
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# Contact information

### Type(s)
Principal Investigator

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
2020-05205

# Study information

### Scientific Title
Influence of exercise duration on respiratory responses to exercise in sub-zero conditions

### Study objectives
The aim of the study was to examine how two different exercise sessions, of matched intensity but different duration, performed in a sub-zero environment, affect:
1. Lung function
2. Local biomarkers of airway damage
3. Systemic markers of airway epithelial damage and transient immunomodulation
4. Post-exercise respiratory symptoms.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 11/12/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref 2020-05205

### Study design
Randomized cross-over trial

### Primary study design
Interventional

### Secondary study design
Randomised cross over trial

### Study setting(s)
Other

### Study type(s)
Other

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

### Health condition(s) or problem(s) studied
Respiratory responses to exercise in cold in healthy individuals; prevention of exercise-induced bronchoconstriction and respiratory symptoms.

### Interventions
Participants performed a preliminary test to determine their maximal oxygen uptake and running speed to elicit 60% maximal oxygen uptake, followed by two experimental trials. During the trials, participants performed running exercise at 60% of maximal oxygen uptake in an

environmental chamber at -15C, on two occasions. The duration of the exercise bouts differed between trials (30 vs 90 min). Participants performed the two exercise trials in a randomized order, participants were block randomized in block sizes of 2, using a coin toss to determine the trial order for every other participant. All measurements for each trial were completed within 24h, and participants had a washout period of at least 48h in between trials.

### Intervention Type
Behavioural

### Primary outcome measure
1. Lung function (spirometry: FEV1, FVC, FEV1/FVC; impulse oscillometry: R5, R20 and X5); pre, 12 and 50 min post-exercise.
2. Lower airway (4-item, YES/NO) and cold-induced symptoms (9 item questionnaire, Borg CRE scale): pre, post, 20 min and 24h post-exercise.
3. White cell counts using blood test (pre, 10 min post and 65 min post-exercise)
4. Blood biomarkers of airway epithelial damage (serum CC-16) using blood test (pre, 10 min post and 65 min post-exercise)

### Secondary outcome measures
1. Atopic or non-atopic determined using AQUA© (cut off score ≥5) at the preliminary visit
2. Exhaled particle count and analysis (exploratory analysis; collected pre and 20-30 min post-exercise; particle counts and mass as well as possible mass spectrometry analysis ('omics'))
3. Other biomarkers from biobank serum samples (HSP70; Eotaxin, Periostin, 8-isoprostane; or other immune/inflammatory markers; pre, 10 min post and 65 min post-exercise)

### Overall study start date
01/09/2020

### Completion date
31/03/2021

## Eligibility

### Key inclusion criteria
1. Age 18-45 years
2. Undertaking regular endurance training, including a prolonged session (>90 min) at least once every 3 weeks

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
45 Years

### Sex
Both

### Target number of participants
20

### Total final enrolment
18

### Key exclusion criteria
1. Never have trained/competed at elite level in an endurance sport
2. Smoker
3. History of chronic asthma, current asthma diagnosis and/or cardiovascular or chronic inflammatory disease
4. Respiratory symptoms 48h prior to each trial
5. (Female participants): not pregnant or breastfeeding, pre-menopausal

### Date of first enrolment
01/01/2021

### Date of final enrolment
01/03/2021

## Locations

### Countries of recruitment
Sweden

### Study participating centre
**Mid Sweden University**
Swedish Winter Sports Research Centre
Studentplan 4
Östersund
Sweden
831 40

## Sponsor information

### Organisation
Mid Sweden University

### Sponsor details
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**Sponsor type**
University/education

**Website**
http://www.miun.se/en

**ROR**
https://ror.org/019k1pd13

# Funder(s)

**Funder type**
Government

**Funder Name**
Östersunds Kommun

# Results and Publications

**Publication and dissemination plan**
Manuscript 1: Primary outcome measures and atopy sub analysis, completed January 2022.
Manuscript 2: Exhaled particle data, tbc.
Possible follow up analyses: Additional biomarkers from blood and exhaled particle samples in biobank.

**Intention to publish date**
01/01/2022

**Individual participant data (IPD) sharing plan**
We do not have ethical approval nor participant consent to publicly share individual participant-level data from this study. Data are available on request with appropriate justification i.e. peer review.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 12/05/2022 | 16/05/2022 | Yes | No |