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

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
31/01/2022		☐ Protocol		
Registration date		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 helen.hanstock@miun.se

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

- 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)

Key secondary outcome(s))

- 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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

45 years

Sex

All

Total final enrolment

18

Kev 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

ROR

https://ror.org/019k1pd13

Funder(s)

Funder type

Government

Funder Name

Östersunds Kommun

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes