ISRCTN10018222 https://doi.org/10.1186/ISRCTN10018222

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

Submission date
27/02/2019

Recruitment status
No longer recruiting

Registration date
01/04/2019

Overall study status
Completed

Last Edited
01/11/2024

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
2x2 cross-over study

Study setting(s)
Other

Study type(s)
Prevention

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
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 makers: 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 makers: 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 measure
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.

Secondary outcome measures
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_4 and 11β-PGF2α pre and 60 min post exposure

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Previous secondary outcome measures as of 20/06/2019:

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

_____

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-1β, IL-6, and TNF-α) 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

Overall study start date
12/06/2018

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

Age group
Adult

Sex
Both

Target number of participants
20

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
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831 40

Study participating centre
Public Health and Clinical Medicine Umeå University
Umeå
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Sponsor information

Organisation
Mid Sweden University

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Sponsor type
University/education

Website
https://www.miun.se

ROR
https://ror.org/019k1pd13

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Sponsor type
University/education

Website
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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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. One manuscript is planned for 2020 and the second during 2020-2021.

Intention to publish date
01/12/2021

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?
Results article		29/03/2021	17/08/2022	Yes	No
Results article		07/04/2022	17/08/2022	Yes	No