ISRCTN79432558 https://doi.org/10.1186/ISRCTN79432558

Cold air, physical activity and the airways

Submission date
08/05/2017

Recruitment status
No longer recruiting

Registration date
09/05/2017

Overall study status
Completed

Last Edited
15/09/2021

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Studies have shown that exposure to sub-zero temperatures is associated with increased morbidity (illness) and mortality (death). People with lung diseases are a particularly vulnerable group. Elite skiers are frequently exposed to cold, dry air and have an increased prevalence of asthma. The prevalence of asthma is 9% in the Swedish population and around 30% among Swedish elite skiers. This study aims to find out whether exercise in -10°C causes more airway symptoms, airway obstruction and higher levels of a marker of airway damage (CC16), compared to exercise in +10°C. The study also aims to find out whether exercise in -15°C, as compared to rest, causes more airway symptoms, airway obstruction and higher levels of CC16.

Who can participate?
Healthy volunteers aged 18-65

What does the study involve?
In the pre-test participants' oxygen uptake and heart rate are measured during a treadmill running test. In the first sub-study, participants are randomly allocated to run on a treadmill in a cold chamber at either +10°C or -10°C. Participants repeat the test at least one week later at the other temperature. In the second sub-study, participants are randomly allocated to either run on a treadmill or be at rest in a cold chamber at -15°C. Participants repeat the test at least one week later performing the other activity. Each test lasts 60 minutes. During each test the participants fill out questionnaires about their symptoms. Before and after each test participants' lung function is assessed and markers of airway damage are measured by taking blood and urine samples.

What are the possible benefits and risks of participating?
The participants receive financial compensation of about £90 (SEK 1000). The pre-test requires exercise to exhaustion which may be uncomfortable for participants who do not frequently undertake high-intensity exercise. Oxygen uptake is measured using a mouthpiece and nose clip that might cause a little discomfort during exercise. Exposure to sub-zero temperatures is expected to cause short-lived cold-related symptoms. Blood sampling causes short-lived pain at the site of vein puncture. The lung function tests involve several large exhalations which may feel exhaustive in the moment.

Where is the study run from?
Swedish Winter Sports Research Centre, Mid Sweden University (Sweden)

When is the study starting and how long is it expected to run for?
January 2016 to June 2018

Who is funding the study?
1. VISARE NORR Fund, Northern Country Councils Regional Federation (Sweden)
2. Unit of Research, Education and Development, Region Jämtland Härjedalen (Sweden)
3. Syskonen Perssons Donationsfond (Sweden)
4. ARCUM, Arctic Research Centre at Umeå University (Sweden)
5. Anna Cederbergs Stiftelse (Sweden)
6. The Swedish Winter Sports Research Centre, Mid Sweden University (Sweden)

Who is the main contact?
1. Dr Linda Eriksson (public)
2. Dr Nikolai Stenfors (scientific)

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H7/H8

Study information

Scientific Title
In healthy individuals, do moderate-hard physical activity in sub-zero temperature damage the airways (measured by lung function and biochemical markers)?

Study objectives
1. Does running in -10°C in a cold chamber cause airway symptoms, airway obstruction, and raised levels of CC16 in blood and urine?
2. Does moderate-hard physical exercise during exposure for -15°C cause, as compared to rest, more airway symptoms, airway obstruction, and higher levels of CC16 in blood and urine?
3. Are there correlations between symptoms triggered by cold temperature, airway obstruction, and levels of CC16 in blood and urine?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Board of Umeå. Department of Medical Research, 22/06/2016, ref: Dnr 2016-203-31M

Study design
Single-centre interventional randomised double-blind 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 the contact details to request a patient information sheet (only available in Swedish)

Health condition(s) or problem(s) studied
Airway injury

Interventions
The study includes 60 healthy individuals, 30 in each sub-study (H7 and H8). Before the exposures, the participants perform a pre-test consisting of an incremental treadmill running protocol until exhaustion. Oxygen uptake and heart rate will be measured throughout the test. Based on the test the participant's VO2 max (maximum oxygen uptake) is calculated. The experimental cold exposures are performed in a cold chamber at the Swedish Winter Sports Research Centre, Mid Sweden University, Östersund, Sweden. Each exposure is 60 minutes.

In sub-study one (H7) the participants are exposed to +10°C and -10°C in randomised order, with at least one week in between the occasions. During the exposures, they run on a treadmill at 60-85% of their VO2 max.

In sub-study two (H8) the participants are exposed to -15°C at two occasions with at least one week in between. During one exposure they are at rest and during one exposure they run on a treadmill at 60-85% of their VO2 max.

Before, during, and after the exposures the participants complete questionnaires regarding symptoms. Immediately before and after the exposures the participants undergo dynamic spirometry and impulse oscillometry. Blood and urine samples are taken immediately before and 60 minutes after the exposures. The blood is sent for the analysis of cell differential count and CC16 and the urine is sent for the analysis of creatinine and CC16.

Added 10/06/2019:
A sample size calculation has been conducted using ΔFEV1 as the primary outcome variable. It is assumed that mean (SD) FEV1 will be 4.58 (0.40) L, and that exercise in -15°C without a breathing mask will decrease FEV1 by 6% (Kennedy and Faulhaber, 2018; Therminarias et al., 1998). The researchers assume equal variance of FEV1 and a correlation of 0.3 between both exposures. The null hypothesis is no difference in the reduction of FEV1 post exposures and they reject the null hypothesis at a 6% reduction of FEV1. With alpha at 0.05 and beta at 0.20, 20 study subjects are required. In statistical analyses, consideration will be taken that the observations are dependent and that there are multiple measurements.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 10/06/2019:
Forced expiratory volume in one second (FEV1) - a measure of lung function, assessed using dynamic spirometry and impulse oscillometry immediately before and after the exposures

Previous primary outcome measure:
CC16 levels, assessed using blood and urine samples taken immediately before and 60 minutes after the exposures

Secondary outcome measures

Current secondary outcome measures as of 10/06/2019:
1. General symptoms and symptoms of the upper and lower airways, assessed using two validated questionnaires before, during (after 10, 30 and 45 minutes), and after the exposures
2. CC16 levels, assessed using blood and urine samples taken immediately before and 60 minutes after the exposures
3. Systemic inflammatory response, assessed by taking blood samples for cell differential count immediately before and 60 minutes after the exposures

Previous secondary outcome measures:
1. General symptoms and symptoms of the upper and lower airways, assessed using two validated questionnaires before, during (after 10, 30 and 45 minutes), and after the exposures
2. Lung function, assessed using dynamic spirometry and impulse oscillometry immediately before and after the exposures
3. Systemic inflammatory response, assessed by taking blood samples for cell differential count immediately before and 60 minutes after the exposures

Overall study start date
01/01/2016

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Healthy volunteer
2. Age 18-65
3. No allergy or asthma
4. Never regular smoker

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20+20

Total final enrolment
76

Key exclusion criteria
1. Asthma
2. Allergy
3. Cardiovascular disease
4. Anti-inflammatory medication
5. Regular smoker or former regular smoker
6. <18 or >65 years of age
7. Recent airway infection (<4 weeks prior to pretests and exposures)

Date of first enrolment
01/09/2016

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
Sweden

Study participating centre
The Swedish Winter Sports Research Centre, Mid Sweden University
Östersund
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Sponsor information

Organisation
Umeå University

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Not defined

Funder Name
VISARE NORR Fund, Northern Country Councils Regional Federation

Funder Name
Unit of Research, Education and Development, Region Jämtland Härjedalen

Funder Name
Syskonen Perssons Donationsfond

Funder Name
ARCUM, Arctic Research Centre at Umeå University

Funder Name
Anna Cederbergs Stiftelse för Medicinsk Forskning

Alternative Name(s)
Anna Cederberg's Foundation for Medical Research, Anna Cederberg Foundation for Medical Research, Anna Cederberg Foundation, Anna Cederbergs Stiftelse

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name

Results and Publications

Publication and dissemination plan
Publication of the results in articles in medical scientific journals during 2018-2019. The articles will be part of a thesis with planned dissertation in 2021.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data generated during and/or analysed during the current study are not expected to be made available due to a requirement in the ethical approval, where there is a statement that the data will not be shared with unauthorized persons. The data will be held at a server at Umeå University.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		25/06/2019	25/06/2019	No	No
Results article		08/03/2021	15/09/2021	Yes	No