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Airways symptoms of exposure to cold air

Submission date	Recruitment status	[_] Prospectively registered
05/04/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/04/2019	Respiratory	

Plain English summary of protocol

Background and study aims
Exposure to cold air is associated with increased morbidity (disease) and mortality (death) in the general population. Exposure to extreme cold weather can cause shivering, tiredness, changes in breathing. It can lead to hypothermia (which means their body temperature drops to dangerously low levels) and hypoventilation (slow breathing). It is difficult to study effects of whole-body exposure to cold air under controlled conditions in real life due to safety issues. The aim of this study is to develop a controlled setup to allow investigation of human airway responses of exposures to subfreezing temperatures and compare the impact of the weather on participants with different respiratory issues.

Who can participate?
Adults aged 18 and older who are either healthy, have allergies, are asthmatic, have COPD or are elite skiers.

What does the study involve?
Participants undergo an exercise test to predict their maximum rate that they use oxygen during exercise. Participants are randomly allocated to be exposed to the either 0 °C, -10 °C and -20 °C over three separate sessions at least one week apart. Each exposure session consists of alternating 15 minute periods of upright resting and walking for one hour on a treadmill at a speed that is predicted to cause participants to use 50% of their maximum oxygen levels. General and airway symptoms are recorded using participant interviews during the exposures sessions.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. There is a risk of developing common temporary symptoms associated with exposure to cold air such as rhinorrea (runny or stuffed nose), dyspnea (difficulty breathing), cough, and a general feeling of cold.

Where is the study run from?
Östersund Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
1. Gunhild och Assar Karlssons Donations Fund (Sweden)
2. Region Jämtland Härjedalen (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3

Study information

Scientific Title
A qualitative study of airways symptoms of experimental exposure to cold air

Study objectives
1. Experimental exposure to cold air induces airway symptoms
2. The airway symptoms are correlated to exposure temperature
3. Visavi symptoms, healthy subjects differ from subjects with allergic rhinitis and/or obstructive lung disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board Umeå University, 2015-10-06, ref: dnr 2015/245-31

Study design
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
See additional files (in Swedish)

Health condition(s) or problem(s) studied
Allergic rhinitis, asthma, COPD

Interventions
Participants undergo a ramped maximum exercise test on a motorised treadmill to predict their maximum oxygen consumption (VO2max). Participants are allocated to one of five groups based on their diagnoses or their specifications.

1. Healthy group
2. Allergic rhinitis group
3. Asthma group
4. COPD group
5. Elite Skier group

Participants in each of the groups are randomly exposed to either a 0 °C, -10 °C and -20 °C environmental chamber over three separate occasions at least one week apart. Each exposure session consists of alternating 15 minute periods of upright resting and walking for one hour on a treadmill at a speed that is predicted to elicit 50% of the participants VO2max.

Participants are monitored for their general and airway symptoms through participant interviews during each of the exposures.

Intervention Type
Other

Primary outcome measure

General and airways symptoms are recorded by focused open interviews (symptom intensity is measured using the Borg CR10 scale) at session one, two and three.

Secondary outcome measures
Group comparison of airway symptoms are measured using focused open interviews using the Borg CR10 scale at session one, two and three.

Overall study start date
01/01/2015

Completion date
01/05/2018

Eligibility

Key inclusion criteria
Healthy group:
1. Non-smokers
2. No allergy or respiratory disease
3. Not on medication
4. Aged 18 and older

Allergic rhinitis group:
1. Non-smokers
2. Symptoms of allergy to common airborne allergens
3. Positive skin prick test
4. Aged 18 and older

Asthma group:
1. Non-smoker
2. Physician-diagnosed asthma (stable)
3. Regular use of asthma medications in the past three months
4. Aged 18 and older

COPD group:
1. Physician diagnosed COPD
2. Current or former smoker (at least ten pack years)
3. FEV1/FVC <0.7 and FEVI <80% of predicted post bronchodilation
4. Daily use of COPD pharmacotherapy for the last three months
5. Aged 18 and older

Elite Skier group:
1. Competitive skiers
2. >400 training hours/year
3. No allergy or asthma
4. Aged 18 and older
5. Non-smokers

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8-20 in each group

Key exclusion criteria
Recent airway infection

Date of first enrolment
01/01/2016

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Östersund Hospital
Kyrkgatan 16
Östersund
Sweden
83183

Sponsor information

Organisation
Umeå University

Sponsor details
901 87
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Sponsor type

University/education

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Charity

Funder Name
Gunhild och Assar Karlssons Donations Fund

Funder Name
Region Jämtland Härjedalen

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/10/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to a requirement in the ethical approval there is statement that the data would not be shared to unauthorised persons. The dataset 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?
Participant information sheet		07/04/2017	19/04/2017	No	Yes
Results article	results	01/12/2019	08/04/2019	Yes	No