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# Screening of exercise-induced asthma using exercise in subzero temperature air

**Submission date**
20/09/2022

**Recruitment status**
No longer recruiting

**Registration date**
29/09/2022

**Overall study status**
Completed

**Last Edited**
08/10/2025

**Condition category**
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
Winter sports athletes have a high prevalence of physician-diagnosed asthma. In athletes, the diagnosis often requires objective tests for bronchial hyperresponsiveness (BHR)/exercise-induced bronchoconstriction (EIB), key components of asthma. The exercise-challenge test is the most specific challenge test for athletes. However, we have very little knowledge of the prevalence of BHR/EIB to exercise challenges in subzero temperature air, a common environment for winter sports athletes.

Who can participate?
Current or former students at Swedish National Elite Sports Schools in cross-country skiing and biathlon participating in a survey on heat- and moisture-exchanging breathing masks, airway symptoms, and asthma 2022-2023 and from 2024 students at Swedish National Elite Sports Schools in cross-country skiing and biathlon

What does the study involve?
Exercise-challenge test at -15 degrees Celsius. FeNO, blood and urine sampling, and lung function tests.

What are the possible benefits and risks of participating?
The possible benefits include the diagnosis of BHR/EIB to exercise and cold air. The possible risks include exercise- and cold air-induced discomfort, and local pain from venipuncture.

Where is the study run from?
Umeå University (Sweden)

When is the study starting and how long is it expected to run for?
January 2021 to October 2024

Who is funding the study?
1. Regional Government Jämtland Härjedalen (Sweden)
2. Swedish Heart-Lung Foundation (Sweden)

Who is the main contact
Dr Nikolai Stenfors
nikolai.stenfors@umu.se

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Nikolai Stenfors

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https://orcid.org/0000-0002-1684-1301

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# Additional identifiers

### Protocol serial number
Version 1, 2022-04-20

# Study information

### Scientific Title
Screening of exercise-induced bronchoconstriction using exercise challenge in subzero temperature air

### Acronym
Aegis 4

### Study objectives
Estimate the prevalence of exercise-induced bronchoconstriction in cross-country skiers using exercise challenge in subzero temperature air

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 01/06/2022, Swedish Ethical Review Authority (Box 2110, 750 02 Uppsala, Sweden, +46 10 475 08 00, registrator@etikprovning.se, ref: 2021-02660

## Primary study design
Observational

## Study design
Single-centre prospective screening study

## Study type(s)
Screening

## Health condition(s) or problem(s) studied
Exercise-induced bronchoconstriction

## Interventions
Current interventions as of 16/09/2024:
Study participants were invited by randomization from a list of study subjects participating in a web survey on airway symptoms and asthma among cross-country skiers 2022-2023.

From 2024 study participants are invited by an open invitation to all Swedish National Sport schools in biathlon and cross-country skiers.

Exercise challenge for 8 minutes on a treadmill at -15 Celsius, ~65 % relative humidity and absolute humidity around 1.3g/m3, in an environmental chamber. The exercise challenge involves a rapid increase in treadmill speed and inclination with a target heart rate of >85% (group 1) or >95% (group 2) of the predicted maximum (220-age in years). The target heart rate is maintained for 4-6 minutes.

Previous interventions as of 07/09/2023:
Study participants were invited by randomization from a list of study subjects participating in a web survey on airway symptoms and asthma among cross-country skiers.

Exercise challenge for 8 minutes on a treadmill at -15 Celsius, ~65 % relative humidity and absolute humidity around 1.3g/m3, in an environmental chamber. The exercise challenge involves a rapid increase in treadmill speed and inclination with a target heart rate of >85% (group 1) or >95% (group 2) of the predicted maximum (220-age in years). The target heart rate is maintained for 4-6 minutes.

Previous interventions:
Study participants were invited by randomization from a list of study subjects participating in a web survey on airway symptoms and asthma among cross-country skiers.

Exercise challenge for 8 minutes on a treadmill at -15 Celsius, ~65 % relative humidity and absolute humidity around 1.3g/m3, in an environmental chamber. The exercise challenge involves a rapid increase in treadmill speed and inclination with a target heart rate of >85% of the predicted maximum (220-age in years). The target heart rate is maintained for 4-6 minutes.

## Intervention Type
Other

## Primary outcome(s)
Prevalence of exercise-induced bronchoconstriction, defined as the maximal reduction in FEV1 of >= 10%, measured using dynamic spirometry 5, 10, 15, 20, and 30 minutes post challenge

### Key secondary outcome(s)
Prevalence of exercise-induced bronchoconstriction, defined as the maximal increase in airway resistance (R5) of >= 40%, measured using impulsoscillometry at 3,8,13,18, and 28 minutes post challenge

### Completion date
24/10/2024

## Eligibility

### Key inclusion criteria
Current or former students at Swedish National Elite Sports Schools in cross-country skiing and biathlon participating in a survey on heat- and moisture-exchanging breathing masks, airway symptoms, and asthma.

Added 16/09/2024:
From 2024 and onwards, eligible subjects are restricted to students at Swedish National sport schools in biathlon and cross-country skiing.

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
15 Years

### Sex
All

### Total final enrolment
59

### Key exclusion criteria
Airway infection within 4 weeks prior to exercise challenge

### Date of first enrolment
01/09/2022

### Date of final enrolment
24/10/2024

## Locations

### Countries of recruitment

Sweden

**Study participating centre**
**Dept of Medicine**
Umeå University
Umeå
Sweden
90187

**Study participating centre**
**Department of Health Sciences**
Mid Sweden University
Östersund
Sweden
83125

**Study participating centre**
**Department of Quality Management and Mechanical Engineering**
Mid Sweden University
Östersund
Sweden
83125

# Sponsor information

**Organisation**
Umeå University

**ROR**
https://ror.org/05kb8h459

# Funder(s)

**Funder type**
Government

**Funder Name**
Region Jämtland Härjedalen

### Alternative Name(s)

### Funding Body Type
Government organisation

### Funding Body Subtype
Local government

### Location
Sweden

### Funder Name
Hjärt-Lungfonden (Swedish Heart-Lung Foundation)

### Alternative Name(s)
Swedish Heart-Lung Foundation, Hjart Lungfonden

### Funding Body Type
Private sector organisation

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

### Location
Sweden

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Nikolai Stenfors, nikolai.stenfors@umu.se. Anonymised individual participant data (demographics, lung function, exercise performance, blood/urine samples, questionnaire data and FeNO) can be shared upon request but only for research conducted by Universities and if the research study has been approved by an ethics committee.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 3.0 | 17/06/2021 | 23/09/2022 | No | Yes |
| Protocol file | | 21/04/2021 | 23/09/2022 | No | No |