

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
20/09/2022	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
29/09/2022	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
08/10/2025	Respiratory	<input checked="" type="checkbox"/> 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
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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

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

Study design

Single-centre prospective screening study

Primary study design

Observational

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.

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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 $\geq 10\%$, 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 $\geq 40\%$, 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		21/04/2021	23/09/2022	No	No