ISRCTN12919627 https://doi.org/10.1186/ISRCTN12919627

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

Submission date
20/09/2022

Recruitment status
Recruiting

Registration date
29/09/2022

Overall study status
Ongoing

Last Edited
16/09/2024

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 December 2026

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

ORCID ID
http://orcid.org/0000-0002-1684-1301

Contact details
Building 10
5th floor
Östersund hospital
Östersund
Sweden
83183
+46 70 6092778
nikolai.stenfors@umu.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
University/medical school/dental school, Other

Study type(s)
Screening

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
01/01/2021

Completion date
31/12/2026

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

Age group
Mixed

Lower age limit

15 Years

Sex
Both

Target number of participants
100

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

Date of first enrolment
01/09/2022

Date of final enrolment
01/11/2026

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

Sponsor details
Department of Medicine
Umeå
Sweden
90187
+46 90 7865000
info.folkhalsa@umu.se

Sponsor type
University/education

Website
https://www.umu.se/english

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

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

Intention to publish date
31/12/2027

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