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Investigating conditions causing breathlessness in athletes

Submission date	Recruitment status	[_] Prospectively registered
27/07/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/09/2025	Respiratory	

Plain English summary of protocol

Background and study aims
Exercise-induced dyspnea (shortness of breath) in athletes is common and is often attributed to asthma. However, all wheeze is not due to asthma and diagnosis and treatment should be based on careful clinical evaluation. Exercise-induced laryngeal obstruction (EILO) is an important differential diagnosis to asthma in athletes. In EILO, the larynx (voice box) is transiently obstructed during exercise resulting in decreased airflow and airway symptoms, typically with a sudden onset followed by rapid cessation when exercise is stopped. EILO is diagnosed with a continuous laryngoscopy during exercise (CLE) test, in which larynx is continuously visualized during peak exercise. This study aims to estimate the prevalence of EILO among athletes and to describe the natural history of EILO. Secondary aims of the study are to describe the prevalence of asthma and to what extent the conditions coexist.

Who can participate?
Healthy athletes at competitive level, 15-35 years of age

What does the study involve?
Participation in the study involves one or two visits at the Clinical Research Centre, where testing is done. Each visit includes a clinical examination by a physician, spirometry (lung function tests), asthma provocation test with a eucapnic voluntary hyperventilation test (EVH), skin prick test (only first visit), questionnaire, and continuous laryngoscopy during exercise (CLE) test.

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?
Clinical Research Centre, Östersund Hospital (Sweden)

When is the study starting and how long is it expected to run for?
April 2014 to November 2017

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)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EILO hos konditionsidrottare.

Study information

Scientific Title

Prevalence of exercise-induced laryngeal obstruction and asthma among athletes

Study objectives
Athletes have a high prevalence of exercise-induced laryngeal obstruction (EILO).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2015, Regional Ethical Review Board Umea (Samverkanshuset Universitetsområdet, 901 87 Umeå, Sweden; +46 (0)90 786 7252; epn@adm.umu.se), ref: Dnr 2015-43-31M

Study design
Single-center longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevalence of exercise-induced laryngeal obstruction (EILO) in athletes

Interventions
Participants undergo a clinical examination by the study physician, dynamic spirometry, eucapnic voluntary hyperventilation test, skin prick test, and continuous laryngoscopy during exercise test (CLE). CLE test includes running on a treadmill at incrementing speed to >90% maximum heart rate, while video recording larynx with a nasal fiberscope.

Intervention Type
Other

Primary outcome measure
Prevalence and natural history of exercise-induced laryngeal obstruction (EILO), defined as laryngeal obstruction at glottic or supraglottic level using a visual scoring system, assessed with continuous laryngoscopy during exercise test (CLE), at the first and second visit (summer or winter season)

Secondary outcome measures

1. Current asthma, defined as a) physician-diagnosed asthma, and b) use of asthma medication in the last 12 months, evaluated by questionnaire at first visit
2. Bronchial hyperreactivity, defined as 10% decrease in FEV1 after EVH test, measured at the first and second visit (summer or winter season)
3. Allergy, defined as a) reaction with >2 mm wheal to skin prick test, and b) self-reported allergic symptoms, measured at first visit

Overall study start date
26/04/2014

Completion date
28/11/2017

Eligibility

Key inclusion criteria
1. Competitive athlete (i.e. not at recreational level)
2. Age 15-35 years

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
15 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
100

Total final enrolment
111

Key exclusion criteria
1. Pregnancy
2. FEV1 <50% of expected value at spirometry
3. Blood pressure (mmHg) > 200 systolic or >100 diastolic at rest
4. Aortic aneurysm
5. Previous heart attack or stroke

Date of first enrolment
07/04/2015

Date of final enrolment
28/11/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Clinical Research Centre, Östersund Hospital
Kyrkgatan 16
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Sponsor information

Organisation
Umeå University

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Sponsor type
University/education

Website
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Funder(s)

Funder type
Government

Funder Name
VISARE NORR Fund, Northern Country Councils Regional Federation

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

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals. Additional documents may be made available upon request.

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 in 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?
Results article		01/06/2021	15/04/2021	Yes	No
Protocol file	In Swedish version 2	29/06/2020	30/08/2022	No	No
Other publications	Longitudinal follow-up	15/07/2023	17/07/2023	Yes	No