Diagnosing exercise induced laryngeal obstruction: The influence of air temperature and humidity on exercise induced laryngeal obstruction (EILO)

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To investigate the influence of air temperature and humidity on the occurrence of EILO. A better understanding of the pathophysiologic principles causing EILO could lead to increased sensitivity of CLE testing. New insights in the causes of EILO can…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON51128

Source
ToetsingOnline

Brief title
EILO: the influence of air temperature and humidity

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
paradoxal vocal fold motion disorder, vocal cord dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Adolescent, Continuous Laryngoscopy during Exercise, Exercise Induced Laryngeal Obstruction (EILO), Temperature

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameter is the difference of occurrence of EILO (defined as Maat sumscore >2) during CLE testing at room temperature and in cold, dry air.

Secondary outcome

-EILO grade score (Maat score; glottic or supraglottic, grade 1-3)

-Symptoms reported

-Duration until start of symptoms after start of exercise, and duration until peak dyspnoea

-VAS score: before exercise, at peak level of dyspnoea and 2 minutes after exercise

-Physiologic measurements: breathing frequency, heart rate, heart rate recovery time, blood pressure

-EMG measurements of diaphragm before and after exercise

-Respiratory induction plethysmography (RIP) during exercise

-Lung function with in- and expiratory flow volume loops before and at 1, 3, 6 minutes after exercise

-FOT measurements before and after exercise

-Audio-visual recordings: breath sounds, observed breathing pattern

-Max Wattage/kg or maximum running pace

-Questionnaire about perceived symptoms and influence of environmental factors

-Astma control test

Study description

Background summary

Exercise induced laryngeal obstruction (EILO) is limiting cause of exertional dyspnoea, and most common in adolescent athletes. EILO is an inappropriate closure of the larynx during strenuous physical activity with no obvious laryngeal pathology at rest. Despite the high prevalence of EILO, pathophysiology and physiological changes preluding EILO are still poorly understood. It is suggested that environmental factors such as cold air play a role in the pathogenesis of EILO (1). EILO can be diagnosed by continuous laryngoscopy during exercise (CLE), during which patients perform an incremental exercise test until symptoms occur while the larynx is continuously visualized. We hypothesize that performing CLE tests in a cold, dry air leads to a higher number of positive tests than performing CLE tests at room temperature. Furthermore, we aim to gain a better understanding of the pathophysiological changes leading up to EILO by collecting detailed physiological data during CLE tests. A better understanding of factors and circumstances triggering and preluding EILO can hopefully guide towards tailored and effective therapeutic options.

Study objective

To investigate the influence of air temperature and humidity on the occurrence of EILO. A better understanding of the pathophysiologic principles causing EILO could lead to increased sensitivity of CLE testing. New insights in the causes of EILO can also lead towards new therapeutic strategies as there is no evidence based therapy regarding EILO yet.

Study design

This study has a prospective, randomized, cross-over design. Subjects suspected to have EILO who are planned for a CLE test will be asked to perform one extra CLE test. One test will take place at room temperature, and one in cold, dry air (5- 10 dgr C) by using a climate chamber. Patients will be randomized into two groups. One group first performs the test at room temperature, and the other group first performs the test in cold, dry air. During the CLE test there will be extensive monitoring of physiological responses to exercise. Patients

will also be asked to fill in a questionnaire about their symptoms and factors eliciting dyspnoea.

Intervention

-Cold, dry air by using a climate chamber (5-10 dgrC)

Study burden and risks

The burden of participating in this study involves one extra CLE test compared to standard care. The test takes about one hour and risks are minimal. Patients will be asked to fill in a questionnaire about their symptoms and perceived influence of environmental factors on their symptoms. The extra measurements by Hexoskin and EMG involve no additional risk, besides a small change of an allergic reaction to EMG stickers. Therefore latex-free stickers are used).
Both Hexoskin and EMG are only used for data collection and are not acted upon yet.
A benefit of participating is the possible higher chance to receive a positive test result. This age group is most suited, since EILO prevalence tends to be highest amongst adolescents. Risks associated with this study are deemed to be low

Contacts

Public
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512KZ
NL
Scientific
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

-Age 10 to 24 years
-Clinical suspicion of EILO and planned for ECT
-Ability to perform exercise challenge test on treadmill or bike
-Written informed consent of patient and/or parents or legal guardians

Exclusion criteria

-Other severe cardiopulmonary disease
-Baseline FEV1 <70 % of predicted
-Use of long acting bronchodilator agents 24 hours before testing
-Use of short acting bronchodilator agents 8 hours before testing

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2022

Enrollment:	31
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77748.000.21