*The prevalence of Exercise Induced Laryngeal Obstruction (EILO) amongst children with asthma *

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

Summary

ID

NL-OMON53261

Source
ToetsingOnline

Brief title
Prevalence of EILO among children with asthma

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
'Exercise Induced Laryngeal Obstruction (EILO)' "Glottic or supraglottic narrowing of the airway during exercise"

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Asthma, Continuos Laryngoscopy during Exercise (CLE), Exercise Induced Laryngeal Obstruction (EILO), Pediatric

Outcome measures

Primary outcome

The presence of EILO based on the Maat score (glottic and/or supraglottic,

grade 2 or higher) during the CLE test

Secondary outcome

-Recognizable symptoms induced : yes/no

-EILO grade score (Maat score; glottic and/or supraglottic)

-Laryngeal pathology at rest

-Exercise induced bronchoconstriction defined as post-exercise fall in FEV1 >

10% during CLE test and during ECT beforehand. (Post-exercise fall in FEV1 =

(FEV1pre-exercise - FEV1post-exercise) / FEV1pre-exercise * 100%).

-Symptoms reported

-Test duration and duration until start of symptoms and until peak dyspnea

-Heart rate during exercise

-Lung function with in- and expiratory flow volume loops (FEV1, FEV1(%pred),

FVC)

-before exercise

-after exercise at 2 minute intervals (1,3,6 minutes)

-Maximum running pace and slope (or max Wattage and Wattage/kg)

-ACT score and sub scores

-EILODI score and sub scores

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

exercise

Study description

Background summary

Exertional dyspnoea is a common and limiting symptom within the paediatric population. Exercise induced bronchoconstriction (EIB) is a well-known cause of exertional dyspnoea and is highly specific of childhood asthma (5). Another less recognized cause of exertional dyspnoea is exercise induced laryngeal obstruction (EILO) (10). It can co-exist with and mimic symptoms of EIB (10). EILO can be diagnosed by continuous laryngoscopy during exercise (CLE) (11). EILO prevalence seemed markedly higher in adults with asthma: up to 25-47%, compared to 8% in the general population. The prevalence of EILO amongst children with asthma has not yet been investigated. If EILO is a significant comorbidity of childhood asthma this would implicate that EILO screening should be considered when exercise is a persistent trigger of symptoms in asthmatic children. We therefore aim to investigate the prevalence of EILO in children with asthma.

Study objective

Our primary objective is to determine the prevalence of exercise induced laryngeal obstruction (EILO) in children with asthma. As secondary objectives, we aim to investigate 1) if there is a different prevalence of EILO in children with and without EIB, 2) if there are baseline or test characteristics associated with the presence of EILO in asthmatic children, 3) if questionnaire scores (ACT, EILODI and/or VAS) are associated with the presence of EILO in asthmatic children, 4) if lung function measurements (LF) with a standardized CLE test protocol are similar to LF measurements with a standardized ECT protocol and 5) the inter-rater reliability of EILO diagnosis between both hospitals based on the video-images of the larynx during exercise

Study design

This study has a cross-sectional design. Asthmatic children perform an Exercise Challenge Test (ECT) and Continuous Laryngoscopy during Exercise Test (CLE test).

Intervention

Continuous laryngoscopy during exercise

Study burden and risks

The burden of participating in this study involves a CLE test. Introduction of the laryngoscope can be unpleasant. Therefore an anaestethic is applied to the nostrils beforehand. The test takes about one hour and risks are minimal. Patients will be asked to fill in two questionnaire during their visit, and a VAS score before exercise, at peak intensity and 2 minutes after exercise. A benefit of participating is chance to become aware of having EILO in addition to asthma. Appropriate therapy by a speech therapist can then be started. Risks associated with this study are deemed to be low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-Age 8 to 18 years old
-Outpatient at Medisch Spectrum Twente or Haukeland University Hospital
-History of paediatrician diagnosed asthma confirmed with objective lung function measurements:
-a positive test for exercise induced bronchoconstriction (post-exercise fall in FEV1 > 10% after exercise challenge test) OR
-a positive methacholine test (PC20 value of <=8 mg/mL) OR
-bronchodilator reversibility (increase in FEV1 >=12% and/or >=200 mL following inhalation of 400 µg SABA)

Exclusion criteria

-Other severe cardiopulmonary disease than asthma
-Inability to perform exercise test and/or technical acceptable spirometry
-Current asthma exacerbation, or exacerbation in the previous 2 weeks
-Respiratory tract infection in the previous 2 weeks
-Use of LABA or SABA less than 8 hours prior to exercise challenge test
-Use of oral corticosteroids in 4 weeks prior to exercise challenge test

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	17-11-2023
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	NL84027.000.23