Assessment of exercise induced respiratory symptoms in children using electromyography

Published: 01-09-2020
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To determine the differences in muscular activity of the diaphragm between children with controlled asthma, uncontrolled asthma, dysfunctional breathing patterns and healthy children.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON49352

Source
ToetsingOnline

Brief title
AEIRSCUE

Condition

- Respiratory tract infections

Synonym
asthma, dysfunctional breathing

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Chiesi Farmaceutici,Chiesi Pharmaceuticals

Intervention

Keyword: asthma, diaphragm, electromyography, non-invasive

Outcome measures

Primary outcome

The changes in muscular activity and spirometry will be compared to their baseline values to determine the decrease in lung function, as well as the increase in muscular activity in response to exercise. Muscular activity will also be compared to spirometry in order to establish the correlation between muscular activity and lung function changes.

Secondary outcome

Non-applicable

Study description

Background summary

Exercise induced bronchoconstriction (EIB) is a highly specific symptom for childhood asthma. The muscular activity of the diaphragm is known to be closely related to the pulmonary function measured with spirometry. We aim to investigate the use of the non-demanding EMG measurements as an alternative measure in childhood asthma.

Study objective

To determine the differences in muscular activity of the diaphragm between children with controlled asthma, uncontrolled asthma, dysfunctional breathing patterns and healthy children.

Study design

The study will have a cross sectional design, in which all children are exposed to the same exercise protocol. Asthma control will subsequently be determined by a paediatrician. Children will perform their scheduled exercise challenge test (ECT). Before the ECT protocol commences, children are equipped with a

portable EMG amplifier. Before standard spirometry measurements, children are asked to sit still for 45 seconds in order to perform EMG measurements. Measurements will be repeated throughout the ECT protocol.

Study burden and risks

Participation in this study does not pose any additional risks to participants, other than the risks involved with the scheduled ECT. Study related patient burden is comprised of two sticky electrodes worn at the height of the diaphragm and a bracelet around one of the arms. The portable amplifier is worn on a belt. The study burden is negligible and no study related risks are present. The study must be performed in children, as exercise induced bronchoconstriction is a highly specific symptom in childhood asthma.

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

exercise induced respiratory symptoms
referred for exercise challenge test at our center
ages between 7 and 18

Exclusion criteria

children and/or parents that do not speak dutch
ICD/pacemaker
co-morbid diseases other than asthma
premature birth (<37 weeks)
psychomotor retardation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2021
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25819
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73398.100.20