Continuous EMG measurements in children with asthma during sleep

Published: 18-11-2022
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To investigate whether electromyography of the diaphragm during sleep in asthmatic children can be used to objectively monitor asthma control.

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

Summary

ID

NL-OMON51592

Source
ToetsingOnline

Brief title
EMG in sleep

Condition

- Respiratory tract infections

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Afstudeerbudget Technisch Geneeskundige Universiteit Twente

Intervention

Keyword: Asthma, Electromyography, Paediatrics

Outcome measures

Primary outcome

Changes in muscle activity are compared before and after administration of

bronchodilator drugs. In addition, it will be examined whether the data

obtained from EMG can be compared with the data from the RIP measurements.

Secondary outcome

Not applicable

Study description

Background summary

Asthma is one of the most common chronic inflammatory diseases in children. One of the characteristics of asthma is that patients experience dyspnea during sleep, if the asthma symptoms are poorly controlled. The combination of poorly-controlled asthma and sleep disorders could be a cause of the lower quality of life experienced by children with poorly controlled asthma. Electromyography (EMG) is used as an experimental tool to measure the activity of the diaphragm in paediatric patients with asthma. EMG could provide easy, passive method for monitoring asthma during sleep.

Study objective

To investigate whether electromyography of the diaphragm during sleep in asthmatic children can be used to objectively monitor asthma control.

Study design

The study will have a cross-sectional design. The measuring equipment is connected during an admission to the paediatric ward. The measurements will take place overnight.

Study burden and risks

The study poses no risks to test subjects. The measurements are taken in addition to regular care according to current guidelines. During this study, subjects are asked to wear a close-fitting shirt with 3 electrodes underneath for 1 night. This examination does not entail any additional burden. The study should be conducted in children, because the asthma population in children is more vulnerable and clearly different from the adult population.

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

Paediatrician diagnosed asthma or bronchial hyperresponsiveness
Aged 4 till 18

Admitted to the paediatric ward of Medisch Spectrum Twente

Exclusion criteria

Admittance to the ICU
Patient has ICD or pacemaker
Parents and/or patient cannot understand or speak Dutch
Does not fit in one of the available Hexoskin shirts

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-03-2023
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-11-2022
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05547477
CCMO	NL81950.100.22