Electromyography Assessing Treatment in Pediatrics

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24834

Source
NTR

Brief title
EATP

Health condition

Astma, bronchial hyper responsiveness and bronchial obstruction

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

EMG parameters correlated to standard lung function test determining its use providing information on the efficiency of treatment

Secondary outcome

The difference in EMG and its recovery between children with less and increased respiratory distress

Study description

Background summary

Quantitative lung function methods, such as spirometry and Forced Oscillatory Technique (FOT), are valuable tools for the pediatrician to assess respiratory physiology. Over recent years, electromyography (EMG), a less demanding and non-obtrusive method, has been studied in the assessment of bronchial hyperreactivity, showing promising results. A change in EMG signal is suggested to reflect respiratory distress. Therefore, the EATP study hypothesizes that changes in EMG signal can reflect treatment response, and may provide clinicians with valuable information on treatment efficacy.

Study objective

EMG measurements will reflect treatment response in children referred to the pediatrics department for bronchial hyper responsiveness and/or obstruction, providing clinicians with valuable information on treatment efficiency

Study design

- When patients with bronchial obstruction and hyperresponsiveness are referred to the outpatient clinic, they are asked to participate upon arrival. Informed consent is obtained as well. If the medical situation surrounding the subject is in a more tranquil state, the subject and parents will have the opportunity to read the information more thoroughly and ask as much questions as needed.
- Measurements are conducted before and after every nasal irrigation and salbutamol administration given according to standard care and before discharge.
- Measurements are repeated in case of mandatory follow-up in one week time.

Contacts

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Eligibility criteria

Inclusion criteria

children with bronchial obstruction and bronchial hyper responsiveness in need of bronchodilator treatment, ages: 4 -16 years

Exclusion criteria

Admittance to ICU, children of parents with insufficient knowledge of the Dutch language, children with a pacemaker/ICD, children born prematurely (<32 weeks of gestation)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-07-2019
Application type:	First submission

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
NTR-new	NL7850
Other	MEC protocol number : K19-29

Study results