The muscle activity of the diaphragm and intercostal muscles in acutely dyspneic children during hospitalization, before and after treatment with salbutamol

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON40181

Source
ToetsingOnline

Brief title
EMG in dyspneic children, before and after treatment with salbutamol

Condition

- Bronchial disorders (excl neoplasms)

Synonym
dyspnea, tightness of the chest

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,inbiolab

Intervention

Keyword: Children, Dyspneic, EMG, Salbutamol

Outcome measures

Primary outcome

The main data obtained in this study are the EMG values **before and after

treatment with Salbutamol in children with acute dyspnea.

Secondary outcome

Secondary outcome measure is the degree of dyspnea. This consists of the

Clinical Asthma Score, determined by the investigator, and the Borg scale,

determined by the parents. Beside, EMG values **of acutely distressed children

will be compared with EMG values **in healthy peers.

Study description

Background summary

Acute dyspnea is common in children younger than 6 years. In this age there are currently few reliable measurement tools to objectively determine. The degree of dyspnea in children with acute dyspnea is often on clinical grounds. In children with acute dyspnea usually started with a trial treatment with salbutamol. In young children it is difficult to objectively determine whether and how large the effect of salbutamol is. Previous research has shown that measuring muscle tone through EMG of the intercostal muscles and diaphragm is feasible in children younger than 6 years. Also the EMG measurements correlated strongly with the values found with the subjective Clinical Asthma Score. This study, however, is done with only a small group of children.

Study objective

In the present study we want to examine the effect of salbutamol on the muscle tone of the diaphragm. We also want to examine the correlation between muscle tension measured by EMG and the Clinical Asthma Score. To include the children

that come to the emergency ward with acute distress, but will not be hospitalized, we also want to measure the muscle tone of the diaphragm in healthy peers, so we have a suitable controle measurement for these children.

Study design

The study is a prospective study. In children who come in the emergency department because of dyspnea will be measured EMG values before and after treatment with Salbutamol. If these children are hospitalized they will be measured on the first three days of hospitalization and on the day of dismissal. With a shorter hospital stay, the remaining measurements canceled and the last measurement will be seen as the measurement for dismissal. In addition, the Clinical Asthma Score is determined and a parent will be asked to indicate on a scale of 1 to 10 the dyspnea of the child. Finally, the parents will be asked to complete a questionnaire. The questionnaire focuses on the history of the child, exposure to tobacco smoke, asthma symptoms and preventing asthma in the family.

The EMG measurements in the control group will take place at the nursery, after school care or school of the child, after obtaining permission from the parents. This will be a single measurement, wherein no Salbutamol will be administered. Finally, these parents will be asked to complete a questionnaire.

Study burden and risks

The EMG measurements as will be performed in this study are painless and minimally stressful. The child will be asked a few moments to lie still.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Research group:
- Children from 0 months to 6 years who present with acute shortness of breath and treated with Sabutamol (sometimes combined with Ipratropium bromide). ;control group:
- Children from 0 months to 6 years
- From a nursery, after school care or school in the province of Groningen and Drenthe

Exclusion criteria

research group:
- Congenital disorders that can cause distress and severe congenital heart disease or cystic fibrosis.
- Status after diaphragmatic hernia
- Allergy to EMG patches
- Prematurity
- Pneumonia ;control group:
- Congenital disorders or acquired diseases that can cause distress and severe congenital heart defects, cystic fibrosis, asthma, pneumonia.
- Use of bronchodilator agents
- Status after diaphragmatic hernia
- Allergy to EMG patches
- Prematurity

Study design

Design

Study type:	Observational 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):	14-02-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL46269.042.13

Study results

Date completed:	01-02-2015
Actual enrolment:	55