# Respiratory sEMG in dyspneic children before and after treatment with Salbutamol.

Published: 08-03-2022 Last updated: 21-12-2024

This study aims to validate the efficacy of a wireless and small EMG sensor as a tool for monitoring asthmatic children. We will analyse differences in diaphragmatic muscle activity as measured with this EMG sensor before and after administration of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

## Summary

### ID

NL-OMON52077

**Source** ToetsingOnline

**Brief title** A Dyspnea Sensor for children

### Condition

• Lower respiratory tract disorders (excl obstruction and infection)

**Synonym** Asthma Dyspnea

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Asthmaware

**Source(s) of monetary or material Support:** Asthmaware financiert het onderzoek. Om dit mogelijk te maken;heeft Stichting Astma Bestrijding een bijdrage toegezegd aan

1 - Respiratory sEMG in dyspneic children before and after treatment with Salbutamol ... 12-05-2025

Asthmaware.

#### Intervention

Keyword: Asthma, Child, Dyspnea, Electromyography

#### **Outcome measures**

#### **Primary outcome**

Primary endpoint is the difference between EMG-measured muscle activity of the diaphragm before and after Salbutamol administration.

#### Secondary outcome

Secondary endpoints are:

• Correlation between the change in EMG-measured diaphragmatic muscle activity

and the change in CAS values in acute dyspnoeic children.

• Correlation between the change in EMG-measured diaphragmatic muscle activity

and the change in Borg values in acute dyspnoeic children.

• Correlation between the change in EMG-measured diaphragmatic muscle activity

and the change in FEV1 values in non-acute dyspnoeic children.

## **Study description**

#### **Background summary**

Asthma is the most prevalent chronic diseases in children. Continuous monitoring of symptoms is essential to reach good asthma control and to enable a child with asthma to live a normal life, without exacerbations and with the lowest possible medication dose. However, currently physicians lack tools to objectively monitor disease activity in the intervals between hospital visits.

Electromyography (EMG) of the diaphragm is a promising technology to objectively monitor dyspnoea in asthmatic children. A wireless and small EMG sensor could be the first step towards availability of this technology for children with asthma.

#### **Study objective**

This study aims to validate the efficacy of a wireless and small EMG sensor as a tool for monitoring asthmatic children. We will analyse differences in diaphragmatic muscle activity as measured with this EMG sensor before and after administration of Salbutamol. We will also investigate correlations between diaphragmatic muscle activity and Clinical Asthma Scores (CAS), Borg scores and FEV1.

#### Study design

Two groups of children will be studied. The first group of children consists of children aged 5-10 years, who have been diagnosed with asthma or are suspected of having the disease. In this study, we will measure their diaphragmatic muscle activity during a standard reversibility test using spirometry at the outpatient clinic of one of the participating hospitals. Their diaphragmatic muscle activity will be measured before, during and after the reversibility testing and Salbutamol administration.

The second group consists of children aged 3-10 years with acute dyspnoea who are treated with Salbutamol in the ER Unit of the Martini Hospital or of the Beatrix Children\*s hospital. During their stay at the ER Unit and (if applicable) the first two days of their stay at the clinic, their diaphragmatic muscle activity will be measured with the EMG sensor, and CAS and Borg scores will be determined.

Neither the researchers nor the caregivers will be able to observe the EMG measurements during the data collection, in order to ensure that care and diagnostic procedures will not be influenced.

#### Study burden and risks

Participants will not be exposed to any substantial risk. The most important burden is the application and removal of three adhesive electrodes on the child\*s skin. The removal might be slightly painful for children.

## Contacts

Public Asthmaware Hendrik Figeeweg 5L Haarlem 2031BJ NL Scientific Asthmaware

Hendrik Figeeweg 5L Haarlem 2031BJ NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

#### Age

Children (2-11 years)

### **Inclusion criteria**

a)

- Diagnosed or suspected with Asthma
- Having a reversibility test scheduled
- Age 5-10 yrs

#### b)

- Acute Dyspnea
- Treated with Salbutamol at the ER Unit
- Age 3-10 yrs

## **Exclusion criteria**

- Congenital diseases that can cause dyspnea, i.e. severe congenital heart defects or Cystic Fybrosis
- History of Herniated Diaphragm
- Allergy of EMG-electrodes
- Ex-prematures with a gestational age at birth <37 wks
- Pneumonia without signs of asthma or bronchial hyperresponsiveness

4 - Respiratory sEMG in dyspneic children before and after treatment with Salbutamol ... 12-05-2025

• Laryngitis subglottica

## Study design

### Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-04-2022
Enrollment:	80
Туре:	Actual

## Medical products/devices used

Generic name:	sEMG Sensor
Registration:	No

## **Ethics review**

Approved WMO	
Date:	08-03-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	21-11-2024
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** CCMO **ID** NL76001.042.22