Wearable cough registration to assess children*s asthma control

Published: 31-07-2018
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To investigate the relation between cough sound characteristics and the ECT-determined asthma control.

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

Summary

ID

NL-OMON46539

Source
ToetsingOnline

Brief title
WEARCough

Condition

- Bronchial disorders (excl neoplasms)

Synonym
bronchial hyper reactivity - asthma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: vanuit Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Asthma, Monitoring, Pediatric, Wearable

Outcome measures

Primary outcome

The main study parameter is to correlate the cough sound parameters to ECT-determined asthma control reflected by the behaviour of the FEV1 during the ECT. The following cough sound parameters will be tested for their correlation to asthma control:

* The amount of coughs executed by the patient, during both day and night.

* The duration of a cough and the duration of its phases, the intensity, skewness, kurtosis, the dominant frequency, fundamental frequencies for the duration of the cough, the power, the spectrogram of the cough and the mel frequency ceptrum.

These parameters will be derived from several measurements:

* From the baseline cough performed prior to the ECT.

* From the cough corresponding to the time instance of the lowest FEV1 of the ECT.

* From the difference between de baseline cough and the cough of the lowest FEV1.

* From the voluntary coughs which were measured during the home-monitoring period.

Secondary outcome

The secondary parameters of this study yield:

* The correlation between the cough sound parameters and asthma control based

on the FOT measurements. FOT based asthma control will be defined as in the statement of the ATS and ERS.67

* The willingness to take part in this study, reflected by the amount of accepted invitations to take part in this study and the amount of invitations send to participate in this study.

* The experience of the patients with wearing the cough measuring device in a non-conventional way, reflected by a questionnaire about the GENEActiv device.

* The correlation of coughs and it*s parameters measured by the GENEActiv device and by sound recordings.

* The change in the cough parameters as a function of FEV1, as measured at home.

* The correlation between voluntary and involuntary coughs, measured in a clinical environment.

* The correlation between in-home measured voluntary and involuntary coughs.

* The correlation of coughs measured by two different accelerometers with different sample frequencies (100 Hz versus 1000 Hz).

* The correlation between the perceived asthma control, as determined by the C-ACT and PAQLQ, and the amount of coughs exerted during the day and during the night.

* The in-patient variances in cough parameters and their accompanying FEV1, due to sleeping.

* The in-patient variances in cough parameters and their accompanying FEV1, due to inhalation of a SABA.

Study description

Background summary

Asthma is a common disease amongst Dutch children, with an occurrence of 23%. In order to achieve good asthma control, regular contact with a health care provider is advised, but however not always feasible. Telehealthcare therefore might offer a solution. The majority of current telehealthcare systems for asthma are based upon questionnaires; while children*s* and parents* perception of asthma control is not always reliable. This research focus on one of the common symptoms of asthma; coughing, which shows promise as a diagnostic tool for asthma.

Study objective

To investigate the relation between cough sound characteristics and the ECT-determined asthma control.

Study design

The study is a observational pilot study and consist of a 1 week home-monitoring period.

Study burden and risks

This research does not have any safety risks or benefits for the subjects. This study is designed to maximize the diagnostic value and minimize the burden of the child. Wearables were chosen based on their paediatric feasibility, size and minimal invasive character; so that subjects will experience a minimal burden during the week of home-monitoring.

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

- Children with paediatrician diagnosed asthma, or children whom are suspected to suffer from asthma, based on reported symptoms and physical examination performed by a physician.
- Children aged between 4 and 14 years old.
- Children whom will receive an exercise challenge test.

Exclusion criteria

* Children who are unable to speak Dutch, or whose legal guardians are unable to speak Dutch.
* Children for whom it is not possible to wear all wearables.
* Children with implanted electrical stimulating devices.
* Children with a known band-aid allergy.
* Children with psychomotor retardation.
* Children with chronic diseases (other than asthma).
* Children whom were born prematurely (* 37 weeks).

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):	03-09-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	31-07-2018
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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: 20576
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65431.044.18
OMON	NL-OMON20576