Wearable cough registration to assess children’s asthma control

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20576

Source
NTR

Brief title
WEARCough

Health condition

Asthma, Bronchial hyperresponsiveness, Children, Astma, Bronchiale Hyperreactiviteit, Kinderen.

Sponsors and support

Primary sponsor: MST Enschede
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

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.

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.

The objective is to find which parameters revealed by cough measurements, reflect the asthma control as assessed by an exercise challenge test (ECT).

Study objective

Physicians will speak of an 'asthma cough' and while coughing is one of the symptoms of asthma, the specificity of coughing as a predictor for asthma is known to be low.
It is hypothesized that the coughs and it's derived parameters, reflect the patients asthma control.

Study design

Every week 3-4 patients are asked to participate.

These patient were recruited based on the already clinically scheduled asthma patient for an exercise challenge test (ECT).

-4 weeks before ECT: recruitment of patients.

-3 weeks before ECT: informed consent.

-2 weeks before ECT: instruction and start using wearables, for 1 week.

-0 weeks before ECT: exercise challenge test

Intervention

- Wearing several devices; an accelerometer for 4 times 12 consecutive hours to measure cough sounds, an accelerometer to monitor physical activity for a full week an wearing of an ECG-device during phsyical activity.

- Using a spirometer whilst wearing the wearables.

- Filling in 3 questionnaires at the end of the monitoring period; the C-ACT, the PAQLQ and a custom questionnaire to evaluate the use of an accelerometer in a non-conventional way.

Contacts

Public
E.C. Klaver
Beekbergen
The Netherlands

Scientific
E.C. Klaver
Beekbergen
The Netherlands

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Children with paediatrician diagnosed asthma, or children whom are suspected to suffer from asthma, based on reported symptoms, atopy and physical examination performed by a physician.

• Children aged between 4 and 14 years old.

• Children whom will receive an ECT.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• 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. For example due to severe skin disease or an amputation of the arm.

• 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

Intervention model: Other

Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated): 15-07-2018

Enrollment: 30

Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46539
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7132

Register	ID
NTR-old	NTR7329
CCMO	NL65431.044.18
OMON	NL-OMON46539

Study results

Summary results
No publications yet.