Wearable cough registration to assess children’s asthma control

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20576

Bron
Nationaal Trial Register

Verkorte titel
WEARCough

Aandoening

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

Ondersteuning

Primaire sponsor: MST Enschede
Overige ondersteuning: Stichting Pediatrisch Onderzoek Enschede

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- 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.

Contactpersonen

Publiek

E.C. Klaver
Beekbergen
The Netherlands

Wetenschappelijk

E.C. Klaver
Beekbergen
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-07-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46539
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7132
NTR-old	NTR7329
CCMO	NL65431.044.18
OMON	NL-OMON46539

Resultaten

Samenvatting resultaten
No publications yet.