Wearable technology to assess children’s asthma control in the home-situation

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23181

Bron
NTR

Verkorte titel
WEARCON

Aandoening

Pediatric asthma / astma bij kinderen
Bronchial hyperresponsiveness (BHR) / bronchiale hyper reactiviteit
Exercise induced bronchoconstriction (EIB) / inspanningsastma

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente (MST, Enschede)
Overige ondersteuning: Stichting Pediatrisch Onderzoek Twente (SPOE)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of this study is the asthma control. This categorical variable will be tested for its agreement with the measured home-measured parameters.

Toelichting onderzoek

Achtergrond van het onderzoek

Asthma is a chronic disease with a high prevalence and high health care costs. Pediatric asthma management is focused on control of asthma symptoms, enabling patients to fully participate in daily life. However, monitoring pediatric asthma is challenging as symptoms are episodic and therefore often absent during clinical visitation. Additionally, children’s expression of asthma symptoms is often difficult to assess and interpret.

Home monitoring of asthma symptoms could be used to provide the physician with more insight into the current asthma status and provide an opportunity to anticipate into the episodically waves of asthma. Therefore this research will focus on home monitoring of asthmatic children with the use of wearable technology.
In this study it will be investigated whether the home measured wearable signals could accurately predict a child's asthma control, compared to the current clinical standard (the exercise challenge test).

Doel van het onderzoek

Home monitoring of asthma symptoms could be used to provide the physician with more insight into the current asthma status and provide an opportunity to anticipate into the episodically waves of asthma. Therefore this research will focus on home monitoring of asthmatic children with the use of wearable technology.

It is hypothesized that asthma control can be accurately determined with home measured signals of the wearables.

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.

-0 weeks before ECT: exercise challenge test.

Onderzoeksproduct en/of interventie

*The use of 4 wearables. ECG recorder, activity tracker, smart inhaler and spirometer for 2 weeks.

*3 questionnaires at the end of each monitoring week. (C-ACT, PAQ-C, PAQLQ)

*Single bio-impedance scale measurement and exhaled breath measurement.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Phase 1 (60 patients):

• Children with paediatric based asthma.

• Children aged between 4 and 14 years old.

• Children that receive an ECT.

Phase 2 (30 healthy controls):

• Healthy children aged between 4 and 14 years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Both phase 1 and phase 2:

• Children with an inability to understand or speak Dutch. This also applies for the parents of all children below the age of 12.

• Children with a pacemaker / implantable cardioverter-defibrillator (ICD) or other electrical stimulation device.

• Children for whom it is not possible to wear all wearables. For example due to severe skin diseases or amputation of the arms etc.

• Children with psychomotor retardation.

• Children with chronic diseases (other than asthma).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	90

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-02-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47316
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6087
NTR-old	NTR6234
CCMO	NL59878.044.16
OMON	NL-OMON47316

Resultaten

Samenvatting resultaten
No publications yet.