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

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

Summary

ID

NL-OMON47316

Source
ToetsingOnline

Brief title
WEARCON

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: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Asthma, Monitoring, Pediatric, Wearable

Outcome measures

Primary outcome

The primary parameter of this study is *asthma control*. A multiple logistic regression will be used to determine which home-monitoring parameters are the most relevant for assessing asthma control in children.

Secondary outcome

Secundary outcomes of this study include: the accuracy and reproducability of the wearables; The clinical feasability of the wearables; The difference of the home-measured parameters between healthy subjects and well controlled asthma patients; The patient perception of their asthma control; The agreement of the Enose measurements with the exercise challenge tests outcome of asthma control;

Study description

Background summary

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, childrens expression of asthma symptoms is often difficult to assess and interpretate.
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 episodical waves of asthma. Therefore this research will focus on home monitoring of asthmatic children with the use of wearable technology.

Study objective

The objective is to find the most effective combination of wearable devices to accurately reflect paediatric asthma control in a home monitoring situation, by studying the relation of the home-measured signals to the currently used exercise challenge tests for assessment of asthma control in children. It is hypothesized that combining wearable home-monitoring devices can provide a reliable tool for assessing asthma control.

Study design

This study is described as an observational pilot study. The study consists of a home-monitoring period of two weeks, which will end with an already planned exercise challenge test (ECT). The study is further divided in two phases; the first one for monitoring the asthma subjects and the second one for healthy subjects.

Study burden and risks

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

Patients with paediatric based asthma.
Patients aged between 4 and 14 years old.
Patients that receive a clinical exercise challange test.;Or:
Healthy subjects aged between 4 and 14 years old.

Exclusion criteria

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).
Children which use puffer medication which do not fit the Cohoro smart inhaler.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2017
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-03-2018
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: 23181
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59878.044.16
OMON	NL-OMON23181