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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON23181

**Source**
NTR

**Brief title**
WEARCON

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente (MST, Enschede)
**Source(s) of monetary or material Support:** Stichting Pediatrisch Onderzoek Twente (SPOE)

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

*Accuracy and reproducibility of the wearable devices.

*Asthma severity in non controlled asthma patients and its relation to the wearable data.

*Patient perception of asthma control.

*The agreement of the Exhaled biomarker measurement with 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, 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).

### Study objective

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.

### 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.

-0 weeks before ECT: exercise challenge test.

**Intervention**

*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.

# Contacts

**Public**
Landbouwstraat 78

M.R. van der Kamp
Enschede
The Netherlands
tel.: 0636200803
**Scientific**
Landbouwstraat 78

M.R. van der Kamp
Enschede
The Netherlands
tel.: 0636200803

# Eligibility criteria

## Inclusion criteria

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.

### Exclusion criteria

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).

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |

**Control:** Active

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-01-2017 |
| Enrollment: | 90 |
| Type: | Anticipated |

# Ethics review

Positive opinion
Date: 14-02-2017
Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 47316
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results

**Summary results**
No publications yet.