# An innovative breath test for better care for children with asthma-like symptoms

Gepubliceerd: 11-10-2018 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

# Samenvatting

#### ID

NL-OMON27561

**Bron** Nationaal Trial Register

Verkorte titel ADEM2 (Asthma Diagnosis with Exhaled Markers)

#### Aandoening

asthma, asthma-like symptoms, preschool wheezing, transient wheeze, viral wheeze

### Ondersteuning

Primaire sponsor: Maastricht University Medical Centre Overige ondersteuning: Topsector TKI-LSH the Dutch Lung Foundation ZonMW NWO

### **Onderzoeksproduct en/of interventie**

#### **Uitkomstmaten**

#### Primaire uitkomstmaten

The main outcome parameter is % of well controlled asthma-like symptoms after 1-year follow-up. The % well controlled asthma-like symptoms during the study period will be based on the validated TRACK questionnaire. This questionnaire is completed by the parents and doctors and specifically developed for use in this age group, independent of the diagnosis. A score of 80 or more is defined as well controlled disease.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

The objective is to study improvement in health gain and costs of care with the application of a breath test in wheezing preschool children. A multicentre RCT in 220 preschool wheezing children will be performed. The participating centres are all located in the Netherlands: UMC-Groningen, UMC-Nijmegen, Maastricht UMC+, RNFM [Research Network Family Medicine Maastricht] and Zuyderland. Exhaled breath will be collected and analysed with the gold standard (GC-MS). An algorithm based diagnosis will be assessed (ADEM1). Children will be randomised into an intervention group (n=110), in which the doctors and parents will be informed about the diagnosis, or a usual care group (n=110) which is masked for the diagnosis. Children diagnosed with asthma in the intervention group will receive medication according to the asthma guidelines, whereas medication use and referral will be avoided in children with a viral wheeze diagnosis. The usual care group will be treated according to the current practice. Children will be followed up until 6 years of age at which age a definite diagnosis (asthma versus viral wheeze) is made.

#### Doel van het onderzoek

1) an early asthma diagnosis with the breath test will improve disease control, quality of life of children and parents, optimise treatment and thereby improve the prognosis of wheezing children. The use of the breath test will considerably reduce unnecessary burden and costs of the health care system by significantly reducing referral to secondary/tertiary care centres, diminishing use of asthma medication in 'viral wheeze' children, and by reducing loss of asthma control/exacerbations/hospital admissions in children with asthma.

2) GC-MS breath test can be developed into a point-of-care breath test which provides immediate results and is affordable for both primary care and specialist care.3) the predictive VOCs of an early diagnosis (discovered in the ADEM1 study) point to important underlying pathogenetic pathways of an early asthma development.

#### Onderzoeksopzet

Primary outcoume : Disease control (TRACK)

Timepoints: baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, final measurements at age 6 years.

Secondary outcomes:

- Side-effects: continuous registration.
- Exacerbation: continuous registration.
- Pharmacotherapy: continuous registration.

- Costs/Healthcare: baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, final measurements at age 6 years.

- Quality of life: baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, final measurements at age 6 years.

- Lungfunction: baseline, 12 months, 24 months, 36 months, final measurements at age 6 years.

- Breath test: baseline, 12 months, 24 months, 36 months, final measurements at age 6 years.

- Growth: baseline, 12 months, 24 months, 36 months, final measurements at age 6 years.

- Atopy/eosinophils, gene expression, immunological cells, microbiome, epigenomics, gene polymophisms.: baseline, final measurements at age 6 years.

- Final diagnosis: final measurements at age 6 years.

#### **Onderzoeksproduct en/of interventie**

Children will be randomised into an intervention group (n=110), in which the doctors and parents will be informed about the diagnosis, or a 'usual care' (control) group (n=110), in which the diagnosis is unknown until the end of the trial. Children diagnosed with asthma in the intervention group will receive medication according to the asthma guidelines, whereas medication use and referral to a specialist can be avoided in children with a viral wheeze diagnosis. The usual care group will be treated according to the current clinical practice.

## Contactpersonen

### **Publiek**

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## Wetenschappelijk

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## **Deelname eisen**

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Children aged between 2 and 4 years old.

- Presence of objectified (by a physician or nurse) complaints of wheezing and shortness of breath.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Recent systemic course of corticosteroids or antibiotics (< 1 month before test)

- Other chronic inflammatory disease than asthma (e.g. inflammatory bowel disease, autoimmune disorders, rheumatoid arthritis)

- Mental disability

- Other chronic diseases (e.g. cardiac disease, congenital lung disease, kidney or liver disease)

- Not able to perform the study procedures adequately.

# Onderzoeksopzet

## Opzet

Туре:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

#### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	220
Туре:	Verwachte startdatum

# **Ethische beoordeling**

Positief advies	
Datum:	11-10-2018
Soort:	Eerste indiening

# **Registraties**

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

# In overige registers

Register	ID
NTR-new	NL7336
NTR-old	NTR7552
Ander register	ZonMW : 848101008

# Resultaten