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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27561

Source
Nationaal Trial Register

Brief title
ADEM2 (Asthma Diagnosis with Exhaled Markers)

Health condition

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

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Source(s) of monetary or material Support: Topsector TKI-LSH
the Dutch Lung Foundation
ZonMW
NWO

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome parameters are pharmacotherapy, growth retardation and other side-effects of medication, exacerbations/hospital admissions, quality of life, lung function, allergy, blood eosinophils, the asthma predictive index (API) index, absence of school and work, healthcare resource use and –costs (standard and extra clinical visits, hospital admissions, referrals), costs outside healthcare, cost-effectiveness, asthma diagnosis at 6 years, gene expression, immunological cells, microbiome, epigenomics, gene polymophisms.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- Children aged between 2 and 4 years old.

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

Exclusion criteria

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

- Other chronic inflammatory disease than asthma (e.g. inflammatory bowel disease, auto-immune 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	220
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7336
NTR-old	NTR7552
Other	ZonMW : 848101008

Study results