

The Rotterdam Asthma Trial

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To determine the effect of protocolled practice nurse-led asthma care for children aged 6 to 12 years old in primary care on asthma control (compared to usual care)

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20109

Source

NTR

Health condition

Asthma in children

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The main study parameter is the overall asthma control in 18 months measured by the Childhood Asthma Control Test (C-ACT)

Secondary outcome

1. C-ACT outcomes during follow-up at 3, 6, 12 and 18 months.
2. Frequency and severity of exacerbations

3. Cost-effectiveness
4. Quality of life assessed by the Standardised Paediatric Asthma Quality of Life Questionnaire (PAQLQ(S))
5. Patient/parent/nurse/GP satisfaction with delivered care
6. Spirometry: FEV1, Forced Expiratory Flow 75 (FEF 75) and reversibility

Study description

Background summary

Objective: To determine the effect of protocolled practice nurse-led asthma care for children aged 6 to 12 years old in primary care on asthma control (compared to usual care).

Study design: This study will be a cluster-randomized open label trial with a follow-up of 18 months, in which the practice nurses will be the units of randomization and children with asthma will be the units of analysis.

Study population: Children with asthma in primary care aged 6-12 years.

Intervention: The practice nurses of the GP-practices will be randomized to protocolled practice nurse-led care, or usual care by the GP.

Main study parameters/endpoints:

Primary objective: to determine the overall treatment effect (0 to 18 months) of protocolled practice nurse-led asthma care for children aged 6 to 12 years old in primary care on asthma control, measured by the Childhood Asthma Control Test (C-ACT) (compared to usual care).

Secondary objectives include C-ACT scores at t=3, t=6 and t=12 months. Frequency and severity of exacerbations, cost-effectiveness, quality of life, patient/caregiver/nurse/GP satisfaction with delivered care, and forced expiratory volume in 1 second (FEV1) and forced expiratory flow 75 (FEF 75).

Study objective

To determine the effect of protocolled practice nurse-led asthma care for children aged 6 to 12 years old in primary care on asthma control (compared to usual care)

Study design

baseline, t=3, t=6, t=12 and t=18 months

Intervention

protocolled nurse led care for children aged 6-12 years. The content of the protocol is based on two Dutch Guidelines for children with Asthma ('NHG guideline' and 'Zorgstandaard')

Contacts

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Eligibility criteria

Inclusion criteria

- Patients who were prescribed one or more times an ICS in the last year.
- Patients who were prescribed 2 or more times a prescription of salbutamol or terbutaline in the last year.
- Children with only one prescription of salbutamol or terbutaline in the last year and a registered ICPC-code for asthma (R96).

Exclusion criteria

- Children receiving asthma treatment from secondary care.
- Children who are not able to perform lung function tests.
- Children with other major chronic diseases (children with atopic conditions such as eczema or allergies are not excluded, since this is a prevalent co-morbidity co-morbidity)
- Children whose parents are unable to understand verbal Dutch instructions or written Dutch questionnaires.

-Children who did not use inhaled asthma medication for at least 6 weeks in the previous year.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	180
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55532
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6677
NTR-old	NTR6847
CCMO	NL63513.078.17
OMON	NL-OMON55532

Study results