

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)

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20109

Bron

Nationaal Trial Register

Aandoening

Asthma in children

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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)

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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')

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55532

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten