Towards better asthma care for children: protocolled practice nurse-led care for children 6-12 years in primary care. A randomized controlled trial.

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The academic network of GPs *PrimEUR* in Rotterdam and the South-West of the Netherlands consists of 12 GP health centers. In addition another 14 GP practices will be recruited. All eligible children aged 6 to 12 years old in the participating GP…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON55532

Source
ToetsingOnline

Brief title
The Rotterdam Asthma Trial.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: asthma, Children, protocolled-care, randomized controlled trial.

Outcome measures

Primary outcome

Primary objective: to determine the overall treatment effect in 18 months 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). The asthma control is measured by the overall treatment effect on the C-ACT.

Secondary outcome

- Symptom control, overtreatment and under treatment in children with asthma in primary care.

- Cost-effectiveness of protocolled practice nurse-led asthma care for children aged 6-12 years compared to usual care in general practice.

- Prognostic factors for high symptoms scores in children with asthma in general practice.

- Quality of life.

- Patient/nurse/GP satisfaction with delivered care

- Asthma control according to GINA guidelines at baseline and t=18 months.

Study description

Background summary

Daily symptoms and exacerbations in children with asthma have significant impact on the quality of life of both the children and the parents. More

effective use of asthma medication is advocated, since over- and undertreatment is reported in primary care. Protocolled care by the General Practitioner (GP) may lead to better asthma treatment in children. There is already a guideline to support this asthma care (*Zorgstandaard*). This guideline recommends planned reconsultations with structured evaluations of individual care-plans and gained goals, making it possible to make alterations in the management of the child*s asthma more proactively. However, this protocolled care by the GP may be time-consuming and therefore less feasible. Protocolled care in general practice supplied by a practice nurse, and under supervision of the GP, may give similar (or even better) improvements in asthma care for children. For diabetes mellitus in primary care it is sufficiently proved that management can be safely transferred to practice nurses. With regard to asthma, a recent systematic review found no significant difference between hospital based nurse-led care for patients with asthma compared to physician-led care.15 However, the relatively small number of included studies limited this review and further research was advised. Besides, only 2 relatively small studies of the in total 5 included studies concerned asthma in children and both of these studies evaluated care by hospital-based specialized asthma nurses and therefore extrapolation of results to primary care is insufficiently supported.

Study objective

The academic network of GPs *PrimEUR* in Rotterdam and the South-West of the Netherlands consists of 12 GP health centers. In addition another 14 GP practices will be recruited. All eligible children aged 6 to 12 years old in the participating GP practices will be invited to participate. Eligible patients will be selected by searching the electronic patient database of GPs for patients who were prescribed one or more ICS, and/or 2 or more prescriptions of salbutamol or terbutaline in the last year. Children with only one prescription of salbutamol or terbutaline and a registered ICPC-code (International Classification of Primary Care code) for asthma (R96) or 'Prikkelbare luchtwegen' (R29.02) are also eligible for inclusion.

Study design

To answer the research questions, we want to conduct a cluster- open label randomized controlled trial with a follow-up of 18 months.

The participating practices with their practice nurse, will be randomized to one of the following treatment arms:
1. Protocolled practice nurse-led asthma care according to the Zorgstandaard18 and the GP- guideline of the NHG of asthma in children.9 Participating practice nurses will receive an up-to-date retraining in protocolled asthma care for children. See chapter *burden* for the recommended follow-up schedule.
2. Usual (GP-led) care.

Besides the randomised part of this trial, we will conduct a non-randomised part of the trial. In this case, children who will receive protocolled nurse-led care by a practice nurse will be selected by the same inclusion and exclusion criteria of the other children in the trial. We will conduct indentical measurements in these children (quuestionnaires and spirometry)

Intervention

Questionnaires and spirometry tests (for more details, see other paragraphs)

Study burden and risks

Nurse-led care has been proven to be safe in other chronic conditions such as diabetes mellitus in adults. No invasive measurements are conducted. In this study, we will conduct two spirometry tests, which, in the opinion of the authors, will cause no additional harm to the children. The implementation of protocolled asthma care for children in primary care may result in a better control of asthma symptoms, may reduce over- an under treatment and misclassification in children. Thus if children get a more efficient treatment for their asthma, they will be less limited in school, sports and daily life. Therefore, the participation of children and the parents is essential for this research.

In the current study, we will conduct two spirometry tests. Reversibility of the FEV1 and the FEF 75 will be tested by administering Salbutamol (inhalation medication).Side effects could occur, however, these symptoms usually only occur when salbutamol is used in higher dosage. In current trial, we will not exceed the maximum dosage. We request the parents of the child to stop bronchodilators before the test. This could lead to a temporarily increase of the symptoms of asthma. However, this is a standard procedure for spirometry and, of course, when it is not possible or medically irresponsible to stop the inhalation medication at that moment we will postpone spirometry.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)

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) or R29.02 'Prikkelbare luchtwegen'

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 other atopic conditions are not excluded, because that is a very common co-morbidity)
Children whose parents are unable to understand verbal Dutch instructions or written Dutch questionnaires.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-07-2018
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	18-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-08-2019
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-10-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-12-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	10-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20109
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63513.078.17
OMON	NL-OMON20109