

Comparison follow up for children with asthma between nurse practitioners, general practitioners and pediatricians.

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Before one could chose for a new organisation form, there should be evidence, that the care provided by such a professional is at least similar to the care provided by the GP or the pediatriacian.The hypothesis of the proposed study is that...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON31090

Source

ToetsingOnline

Brief title

TRAM

Condition

- Bronchial disorders (excl neoplasms)

Synonym

asthma

Research involving

Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis

Source(s) of monetary or material Support: Grant uit Stichting bijzondere activiteiten van het voormalig Ignatius Ziekenhuis

Intervention

Keyword: asthma, children, follow up, nurse practitioner

Outcome measures

Primary outcome

Airway Hyperresponsiveness. (PD20 methacholine)

Secondary outcome

Lungfunction variabels;

- FEV1 before & after beta-2-agonists
- NO in expired air

Patientoriented variabels & health-economics:

- *Asthma Control Questionnaires* plus added quastions (unplanned visits, course of prednison, admission,schoolabsence, workabsence parents)
- Quality of Life Questionnaire.
- Extra referal of *Nurse Practitioner* to pediatrician.
- Extra referal of GP to pediatrician
- Number of consultations in groups A, B & C.
- Medication in de groups A,B & C.

Variabels concerning disease awareness..

- Knowledge of asthma.
- Smoking pattern parents.
- Smoking pattern(teenage) patient.
- Peds.
- Aplication house dust mite isolating matras covers .
- Quality of care children's version.

- Quality of care patient's version.

Study description

Background summary

A *nurse practitioner*, working under supervision, who is specialized in the follow up of children with asthma is a cost-effective solution. Because of the fact, that such a professional is mainly occupied with this specific patient group a wide experience can be built up, guaranteeing quality of care.

The creation of such a professional next to the existing workers in primary and hospital care gives the following advantage:

1. The workload of GP's decreases.
2. Continuity in the follow up of children with asthma
3. Because many children are seen, much experience can be built up guaranteeing quality of care.
4. More cost-effective compared to care provided by extra MD's (scarce and often not available)

Study objective

Before one could choose for a new organisation form, there should be evidence, that the care provided by such a professional is at least similar to the care provided by the GP or the pediatrician.

The hypothesis of the proposed study is that treatment of children with moderate asthma by a *nurse practitioner* working under supervision is not inferior to treatment by GP or pediatrician.

This leads to the following question;

Is follow up of children with moderate asthma by a *nurse practitioner* working under supervision not inferior to treatment by the GP or by the pediatrician?

Study design

Prospective randomised comparing study with three arms, lasting two years.

Intervention

Randomisation:

- Group A: Children with moderate asthma, after confirmation of the diagnosis and after application of the inclusion criteria obtaining usual care by their GP.

- Group B: Children with moderate asthma, after confirmation of the diagnosis and after application of the inclusion criteria obtaining usual care by a specified nurse practitioner, working under supervision of a pediatrician.
- Group C: Children with moderate asthma, after confirmation of the diagnosis and after application of the inclusion criteria obtaining usual care by a pediatrician.

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Children aged 6-16 years

Children with moderate asthma as defined by the guidelines of the dutch pediatric respiratory society of the dutch association for pediatrics and/or children whose general practitioner indicates the use of inhaled corticosteroids as defined by the guidelines of the dutch GP association. Children from general practice as well as pediatric practice can be recruited.

Exclusion criteria

Children who should be referred to a pediatrician for severe asthma, to the judgement of the GP and whose treatment should be continued in pediatric practice

Children unable to perform standard lungfunction testing.

Children with other chronic disease requiring specialistic treatment by a pediatrician.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 11-01-2008

Enrollment: 106

Type: Actual

Ethics review

Approved WMO

Date: 11-01-2008

Application type:

First submission

Review commission:

TWOR: Toetsingscommissie Wetenschappelijk Onderzoek
Rotterdam e.o. (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

No registrations found.

In other registers

Register	ID
CCMO	NL17972.101.07