Development of a general practice-based diagnostic asthma-risk index in young children: Reaping the benefits from an ongoing cohort study.

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To construct a clinical asthma-risk index for 1- to 3 year old children who visit the GP with asthma related complaints. In addition, the effectiveness of two broad treatment strategies (aggressive versus non-aggressive) in children with the same...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON30634

Source
ToetsingOnline

Brief title
ARCADE-II study (AiRway Complaints and Asthma DEvelopment in children)

Condition

- Respiratory tract infections

Synonym
asthma, respiratory symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Nederlands Astma Fonds (heeft subsidie verleend voor uitvoer van ARCADE-II)

Intervention

Keyword: children, diagnostics, observational cohort study, respiratory symptoms

Outcome measures

Primary outcome

The main outcomes in the study are: diagnosis of asthma (lung function test), quality of life, and severity of asthma (expressed in symptoms) at the age of 6. An asthma-risk index will be constructed for 1- to 3 year old children who visit the GP with complaints of recurrent coughing, wheezing or dyspnoea. In addition, we will determine which treatment strategy is most effective.

Secondary outcome

Not applicable.

Study description

Background summary

Asthma is the most frequent chronic illness in children. Asthma is usually diagnosed in general practice. The availability of diagnostic facilities in primary care is limited and not consistent until the age of 6. As a consequence, the GP faces a diagnostic, but also a therapeutic problem in children under 6 with recurrent cough and wheeze.

Study objective

To construct a clinical asthma-risk index for 1- to 3 year old children who visit the GP with asthma related complaints. In addition, the effectiveness of two broad treatment strategies (aggressive versus non-aggressive) in children with the same score on the clinical asthma-risk index will be compared non-experimentally.

Study design

Every time the child presents with airway complaints, the GP scores a number of airway symptoms in a standardized way.
All parents will be asked to complete a questionnaire on asthma symptoms, atopy background, smoking habits, contact with pets and quality of life every 6 months until the children reach the age of 6.
In a subgroup of children, the presence of atopy will be demonstrated by measuring total IgE and specific IgE (RAST) before the fourth birthday.
In the 5-year old children, the measurement of exhaled nitric oxide (NO) and a peak flow will be performed. At the age of 6, a lung function test with metacholine-challenge will be performed.

Intervention

A lung function measurement and a metacholine challenge test will be performed in all 6-year old children with asthma-related complaints or on asthma medication use in the previous year. These measurements are necessary to diagnose asthma. Children who receive asthma medication and have a negative metacholine challenge test will be invited for spirometry and a metacholine challenge test once more. The children on asthma medication use and who are not hyper responsive will be invited to stop their treatment for one month. After this period the children will be invited for spirometry and a metacholine challenge test.

Study burden and risks

A subsample of children under 4 who tested negative at baseline, will be invited for a second measurement of total and specific IgE. Normally, this measurement is determined by a venepuncture. Because of the objections parents and GPs quite often have to obtain blood by a venepuncture, a convenient method (finger prick) for sampling blood and analyses for IgE was developed. With this technique, measurements of total and specific IgE will not be very unpleasant.
In ARCADE we also used this technique without any problems.
All 5-year-old children, will be invited for peak flow and exhaled NO measurements. During a two-week period peak flow will be determined. A peak flow measurement may be an important tool for the GP to diagnose asthma. Peak flow measurement at age 5 could be a good additional diagnostic test to predict asthma which may result that the metacholine challenge test at age 6 necessary. Exhaled NO will be measured off line by blowing in a Mylar balloon. Both measurements are simple and not invasive and will be performed at the hospital or general practice near the childrens' homes.
A lung function measurement and a metacholine challenge test will be performed in all 6-year old children with asthma-related complaints or on asthma medication use in the previous year. These measurements are necessary to diagnose asthma. To determine whether the respiratory tract of the child will be hyperactive, the child will receive little amounts of metacholine. This could result in shortness of breath. When the provocation concentration of

metacholine induces a 20% fall in FEV1 the test will be ended. To increase FEV1 to its normal value the children will receive salbutamol. In rare cases it is possible that children need more salbutamol to increase the FEV1 to its normal value. At all times parents can contact the researchers with questions or for information.
Children who receive asthma medication and have a negative metacholine challenge test will be invited for spirometry and a metacholine challenge test once more. The children on asthma medication use and who are not hyper responsive will be invited to stop their treatment for one month. After this period the children will be invited for spirometry and a metacholine challenge test. The parents of the children will be well informed about the consequences of stopping the treatment or a month. During this period the parents are instructed to consult their GP when the child will develop airway complaints. Medication will only be stopped when the GP of the children gives permission. All the children will receive beta-mimetica. At all time the parents of the children can contact their GP with questions or problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All children who do not reach the age of 6 during ARCADE (children who where included at age 1 to 3), will be asked to participate in ARCADE-II.

Exclusion criteria

There are no exclusion criteria beyond those in ARCADE. No new inclusions will occur, only follow-up.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	580
Type:	Actual

Ethics review

Approved WMO Date:	01-03-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL15387.000.07