Asthma Reduction with Inhaled corticoSteroids in Children with a high risk for the development of asthma (At RISC).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23756

Source
NTR

Brief title
At RISC

Health condition

asthma

Sponsors and support

Primary sponsor: CAPHRI, The Research Institute of the University Maastricht
Source(s) of monetary or material Support: Dutch asthma fundation
AstraZeneca

Intervention

Outcome measures

Primary outcome

The determination of the effect of a course of 1 month budesonide 400 µg MDI via Nebunette and 11 months budesonide 200 µg versus placebo MDI via Nebunette on the development of asthma at the age of 6 years

Secondary outcome

Differences between the group who received treatment with budesonide versus the group who was treated with placebo medication occur in lungfunction characteristics, the body height, the combined asthma score, the presented and reported symptoms and excacerbations, and the adverse events.
- The cost-effectiveness of the treatment, the quality of life with the course of budesonide will be assessed.
- At age 6 changes in control group versus intervention group aren described in the total IgE and the specific IgE for cat, dog, and house dust mite.

Study description

Background summary

The study is a multi-centre, double-blind, placebo-controlled, randomised, parallel group study with a drug intervention period of 12 months with budesonide 200 µg MDI or placebo and a follow-up period of at least 18 months until the children are 6 years old. Children aged 1 - 4.5 years with a familial predisposition for asthma in the first degree, who have experienced at least 2 separate periods with wheeze, confirmed and documented by their GP were included.
Exacerbations during the study period are treated by the responsible GP with standardised care according to explicit guidelines derived from the Dutch NHG guidelines, including using additional medication when necessary.
The GP can ask for help 24 hours a day by one of the involved paediatric pulmonologists. If the patients are still wheezing or presenting other respiratory morbidity after the intervention period they will be treated by the GP according to these standardised NHG guidelines.
All treatments and medication will be exactly recorded in a standardised on-line registration and will be used as outcome.
To support the parents of the participating children 6 homevisits are planned.

Study objective

Asthma reduction at age 6 is possible with inhaled corticosteroids in children of 1-4.5 years old with a familial predisposition for asthma in the first degree, who develop wheeze symptoms.

Intervention

After written parental informed consent has been obtained the children are randomly

assigned to receive one of the following drug treatments during 12 months:

First 4 weeks

- Budesonide 2 puffs 200 µg/puff MDI via Nebunette spacer with appropriate facemask

Next 11 months

- Budesonide 1 puff 200 :g MDI via Nebunette spacer with appropriate facemask

OR

- placebo-to-match-budesonide MDI via Nebunette spacer with appropriate facemask

Contacts

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Eligibility criteria

Inclusion criteria

1. Male and female patients aged 1-4,5 years with a familial predisposition for asthma in the first degree, who have experienced at least 2 separate periods with wheeze lasting at least 2

days each documented by their general practitioner;

2. And for each patient, who enters the study a written informed consent by the parent or guardian of the patient should be obtained.

Exclusion criteria

1. Patients, who have been treated with pulmonary anti-inflammatory inhaled drugs during more than 2 weeks or anti-inflammatory oral drugs during more than 1 week preceding the study. Patients, who have been hospitalised for asthma in the 2 weeks prior to the study;

2. Patients, who have serious respiratory morbidity (e.g. broncho-pulmonary dysplasia, cystic fibrosis, tuberculosis);

3. Patients, who have laboratory or clinical evidence of serious uncontrolled systemic disease (as judged by the investigator);
4. Patients with anatomical abnormalities of the upper airways or lungs;

5. Patients currently participating in another drug intervention study;

6. When the general practioner considers it detrimental to the patient to participate in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2001
Enrollment:	97
Type:	Actual

Ethics review

Positive opinion

Date:	13-09-2005
Application type:	First submission

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
NTR-new	NL358
NTR-old	NTR397
Other	: N/A
ISRCTN	ISRCTN58244066

Study results

Summary results
N/A