

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

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/01/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 25/08/2009	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR397

Study information

Scientific Title

Acronym

At RISC

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised double blind placebo controlled parallel group trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Asthma

Interventions

After written parental informed consent has been obtained the children are randomly assigned to receive one of the following drug treatments for 12 months:

First 4 weeks:

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

Next 11 months:

Budesonide 1 puff 200 ug MDI via Nebunette spacer with appropriate facemask

OR

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

1. Differences between the group who received treatment with budesonide versus the group who was treated with placebo medication occur in lung function characteristics, the body height,

the combined asthma score, the presented and reported symptoms and exacerbations, and the adverse events

2. The cost-effectiveness of the treatment and the quality of life with the course of budesonide will be assessed
3. At age 6 changes in control group versus intervention group are described in the total IgE and the specific IgE for cat, dog, and house dust mite

Completion date

15/01/2008

Eligibility

Key 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. For each patient who enters the study a written informed consent by the parent or guardian of the patient should be obtained

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 Years

Upper age limit

4.5 Years

Sex

All

Key exclusion criteria

1. Patients who have been treated with pulmonary anti-inflammatory inhaled drugs for more than 2 weeks or anti-inflammatory oral drugs for more than 1 week preceding the study
2. Patients who have been hospitalised for asthma in the 2 weeks prior to the study
3. Patients who have serious respiratory morbidity (e.g. broncho-pulmonary dysplasia, cystic fibrosis, tuberculosis)
4. Patients, who have laboratory or clinical evidence of serious uncontrolled systemic disease (as judged by the investigator)
5. Patients with anatomical abnormalities of the upper airways or lungs
6. Patients currently participating in another drug intervention study
7. When the general practitioner considers it detrimental to the patient to participate in the study

Date of first enrolment

10/09/2001

Date of final enrolment

15/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

Care and Public Health Research Institute (CAPHRI), University Maastricht (Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Charity

Funder Name

Netherlands Asthma Foundation (Netherlands)

Funder Name

Astra Zeneca BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration