ISRCTN58244066 https://doi.org/10.1186/ISRCTN58244066

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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 25/08/2009	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Multicentre randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
10/09/2001

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

Age group
Child

Lower age limit
1 Years

Upper age limit
4.5 Years

Sex
Both

Target number of participants
97

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
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Sponsor information

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

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Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration