

Prevention of asthma in children at high risk of developing asthma

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/11/2008	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
NTR371

Study information

Scientific Title
Prevention of asthma in children at high risk of developing asthma by advising parents on reducing environmental exposures

Acronym

PREVASC-OMEGA

Study objectives

Children in the intervention group will show to have less asthma symptoms and a better lung function than children in the control group as measured at age 6 years by questionnaire (symptoms), general practitioners registration (symptoms), and lung function measurements (microRint, FEHO, forced expiratory volume in one second (FEV1), PC20, reversibility).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, single-blind, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Asthma

Interventions

Advisory intervention on reducing exposure to:

1. Allergen exposure (house dust mite, cat and dog allergens)
2. Food allergens by exclusively breastfeeding for a period of 6 months or if not possible feeding the child with hypo-allergenic formula, introducing solids until 6 months
3. Environmental tobacco smoke (parents stop smoking)

Control group: usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Current asthma 6 years as measured in lung function laboratory combined with asthma complaints as registered by General Practitioner and/or parents (questionnaires).

Key secondary outcome(s)

1. Asthma diagnosis by General Practitioner
2. Asthma symptoms 0 - 6 years (questionnaires)

3. Asthma symptoms 0 - 6 years (General Practitioner)
4. Hospital admission for asthma symptoms
5. Allergy (as registered by parents, general practitioner, IgE measurements project)

Completion date

01/07/2007

Eligibility

Key inclusion criteria

General practitioners, midwives and gynaecologists were instructed to check the inclusion criteria:

1. Pregnant women less than 7 months gestational age
2. Unborn child at high risk of developing asthma on grounds of familial predisposition first degree
3. Living in study region

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Major language problem
2. Intrauterine or neonatal death
3. Moving outside the Netherlands
4. Severe illness/malformation child

Date of first enrolment

01/01/1997

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Maastricht (UM)
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation

University Maastricht (UM) (The Netherlands)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name

Netherlands Asthma Foundation (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration