

Prevention of asthma in children at high risk of developing asthma

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/11/2008	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/01/1997

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

Age group

Adult

Sex

Female

Target number of participants

443

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)

Sponsor details

P.O. Box 616

Maastricht

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Sponsor type

University/education

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**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