ISRCTN66748327 https://doi.org/10.1186/ISRCTN66748327

Prevention of asthma in children at high risk of developing asthma

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/11/2008	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof C P van Schayck

Contact details
University Maastricht (UM)
CAPHRI Research Institute
Department of General Practice
P.O. Box 616
Maastricht
Netherlands
6200 MD

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