PREVASC-OMEGA; Prevention of asthma in children at high risk of developing asthma.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27477

Source
Nationaal Trial Register

Brief title
PREVASC-OMEGA

Health condition

asthma

Sponsors and support

Primary sponsor: NAF (Dutch asthma foundation, sponsor)
ZONmw (zorg onderzoek Nederland, sponsor)
Maastricht University, initiator
Source(s) of monetary or material Support: NAF
ZONmw
university hospital Maastricht

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Asthma diagnosis by General Practitioner;

asthma symptoms 0-6yrs (questionnaires);

asthma symptoms 0-6 yrs (General practitioner);

hospital admission for asthma symptoms;

allergy (as registered by parents, general practitioner, IgE measurements project).

Study description

Background summary

In the scope of the PREVASC-study on the PREVention of Asthma in Children, 443 familial predisposed children are being followed from the prenatal period until the age of two years (PREVASC-study, NAF project 96-34, KNAW-fellowship 1997-1999, Prevention Fund project 26-146). These children were randomly allocated to an intervention group or an usual care group. The intervention consisted of advice on measures to decrease the exposure of the child to allergens (house dust mite HDM, cat and dog allergens) and cigarette smoke. Next to these advices, the mothers were stimulated to completely breast feed their child from birth until the age of 6 months and not to start feeding them solid foods until the age of 6 months. For reducing the HDM allergen exposure the children received HDM impermeable mattress covers.
The control group received usual care.
At the time the children have reached the age of two, all parents were approached to continue their participation in the study (OMEGA-study, NAF project 3.2.99.38). After their informed consent was received, the children in the original intervention group were equally divided over two separate intervention groups after randomization. One of the intervention groups was no longer exposed to advice and HDM impermeable mattress covers (short intervention period: 0-2 years; a minimum of 97 children required). The other intervention group continued to be advised about the diminishing of allergen and smoke exposure and was advised to keep on using HDM impermeable mattress covers (extended intervention period: 0-6 years; a minimum of 97 children required). The children that participated in the original control group form the control group of the second part of the study as well and receive usual care (a minimum of 194 children required).

Just like the first part of the study (PREVASC) allergen and cigarette smoke exposure and health problems possibly related to allergic disease and asthma are monitored in all three

groups in the exact same manner. At six years of age (of the child) all parents will receive an invitation to take their child to the hospital to perform lung function tests. The outcome of these lung function tests together with the longitudinally collected data on respiratory morbidity will be used to determine if a child can be labeled as having asthma or not.

Study objective

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, FEV1, PC20, reversibility).

Study design

N/A

Intervention

Advisory intervention on reducing exposure to:
Allergen exposure (house dust mite, cat and dog allergens);

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;

Environmental tobacco smoke (parents stop smoking).

Control group: usual care.

Contacts

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Eligibility criteria

Inclusion criteria

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

1. Pregnant women <7months gestational age;

2. Unborn child at high risk of developing asthma on grounds of familial predisposition first degree;

3. Living in study region.

Exclusion criteria

1. Major language problem;

2. Intrauterine or neonatal death;

3. Moving outside The Netherlands;

4. Severe illness/malformation child.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-01-1997
Enrollment:	443
Type:	Actual

Ethics review

Positive opinion Date:	23-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL333
NTR-old	NTR371
Other	: N/A
ISRCTN	ISRCTN66748327

Study results

Summary results
N/A