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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27477

Bron
Nationaal Trial Register

Verkorte titel
PREVASC-OMEGA

Aandoening

asthma

Ondersteuning

Primaire sponsor: NAF (Dutch asthma foundation, sponsor)
ZONmw (zorg onderzoek Nederland, sponsor)
Maastricht University, initiator
Overige ondersteuning: NAF
ZONmw
university hospital Maastricht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Major language problem;

2. Intrauterine or neonatal death;

3. Moving outside The Netherlands;

4. Severe illness/malformation child.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-1997

Aantal proefpersonen:	443
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A