

# Early detection of asthma-like symptoms in pre-school children at preventive Child Health Centres in the Netherlands

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<b>Registration date</b> 08/12/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/03/2014	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.generationnr.nl/>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

22000128

## **Study information**

### **Scientific Title**

A randomised controlled multicentre interventional trial of early detection of asthma-like symptoms in pre-school children at preventive Child Health Centres in the Netherlands

### **Study objectives**

This study has been set up to evaluate the effectiveness of early detection of asthma-like symptoms in pre-school children at the Child Health Centres. In the short-term the effectiveness will be studied by the frequency of asthma-like symptoms and health-related quality of life. In the long-term the effectiveness will be studied by the frequency of asthma-like symptoms and by the prevalence of doctor-diagnosed asthma.

Please note that this trial is embedded within the Generation-R study, a population-based prospective cohort study from foetal life until young adulthood.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Medical Ethics Research Committee of Erasmus Medical Centre, University Medical Centre Rotterdam, approved on the 9th January 2003 (ref: MEC 217.595/2002/202)

### **Study design**

Randomised controlled multicentre interventional trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Screening

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Asthma-like symptoms

## **Interventions**

16 Child Health Centres in Rotterdam are participating. These Child Health Centres were first stratified for the socioeconomic status of their neighbourhood and then randomised into 8 intervention Child Health Centres, where early detection procedure will be applied, and 8 control Child Health Centres, where no early detection procedure will be done; just routine procedure will be enhanced.

The early detection questionnaire contains 4 questions, based on selected and adapted questions from the International Studies of Asthma and Allergies in Childhood: about frequency of asthma-like symptoms (wheezing, shortness of breath, dyspnoea) last month and last year, medical treatment last month and smoke exposure in direct environment. The physician interviews the parents during the preventive health check at the intervention Child Health Centre at age 14, 24, 36 and 45 months.

At the intervention CHC's, detected children will be managed effectively by non-pharmacological interventions:

1. Referral to the General Practitioner
2. Advice to visit the General Practitioner when asthma-like symptoms return
3. Referral to asthma-nurse
4. Advice: ventilation of the family house and avoidance of allergic/non-allergic triggers
5. Personal advice to prevent smoke exposure to the child
6. Hand out a flyer about the prevention of passive smoking
7. Hand out a flyer with information about asthma disease

At the non-intervention CHC's, detected children will be managed effectively by non-pharmacological interventions (health education: avoidance of a smoky environment, ventilation of the family house and avoidance of allergic/non-allergic triggers) and if necessary referral to the GP or asthma nurse.

Data collection to age 3 years is completed. In principle, data collection goes on till June 2010 and after that a follow-up of 12 months is planned.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. Frequency of asthma-like symptoms-questionnaire (last 4 weeks/12 months): International study of asthma and allergies in childhood/prevention and incidence of asthma and mite allergy (ISAAC/PIAMA) (wheezing, snoring breath, shortness of breath or dyspnoea)
2. Generic health-related quality of life of the child (last 4 weeks): Health Utilities Index 2/3; Child Health Questionnaire-Infant/Toddler

Follow-up:

1. Multi-RAST/Phadiatop-test (blood samples by Generation R): as indicator of allergic sensitisation
2. Micro-Rint: lung function
3. Exhaled nitric oxide (NO): asthmatic airway inflammation

#### Timepoints of measurement:

Age 14 months: preventive health check (June 2003 - June 2007)

Age 24 months: preventive health check (June 2004 - June 2008)

Age 36 months: preventive health check (June 2005 - June 2009)

Age 45 months: preventive health check (June 2006 - June 2010)

Age 5 years: follow-up measurements (November 2008 - November 2012)

In the future, within Generation R, outcomes at older ages, even into adulthood, may be measured.

#### Secondary outcome measures

Doctor diagnosed asthma - (question to parent(s): has a doctor ever diagnosed asthma in your child?)

Data on covariates will be gathered via procedures within the Generation R study from pharmacists, general practitioners, hospitals and questionnaires from parents, given informed consent.

#### Overall study start date

01/07/2002

#### Completion date

31/03/2011

## Eligibility

#### Key inclusion criteria

The Generation R cohort includes 9778 mothers and their children. Of the 9778 women who enrolled in pregnancy, 7893 children participated in the post-natal cohort. The study population of this trial consists of all 7893 children who will be invited for a preventive health check by the 16 participating Child Health Centres in Rotterdam at age 14, 24, 36 and 45 months.

#### Participant type(s)

Patient

#### Age group

Child

#### Lower age limit

14 Months

#### Upper age limit

45 Months

#### Sex

Both

#### Target number of participants

6650 children

**Key exclusion criteria**

Children not participating the Generation R study who visit the 16 participating Child Health Centres in Rotterdam.

**Date of first enrolment**

01/07/2002

**Date of final enrolment**

31/03/2011

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Erasmus MC University Medical Centre Rotterdam  
Rotterdam  
Netherlands  
3000 CA

**Sponsor information****Organisation**

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

**Sponsor details**

Laan van Nieuw Oost Indië 334  
Postbox 93 245  
The Hague  
Netherlands  
2509 AE

**Sponsor type**

Research organisation

**Website**

<http://www.zonmw.nl/>

**ROR**

<https://ror.org/01yaj9a77>

**Funder(s)**

## Funder type

Research organisation

## Funder Name

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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	reliability and validity of the Child Health Questionnaire short form results	01/01/2005		Yes	No
<a href="#">Other publications</a>	questionnaire construct validity	01/02/2005		Yes	No
<a href="#">Results article</a>	reliability and validity of health status measurements results	01/04/2005		Yes	No
<a href="#">Results article</a>	preliminary results	01/10/2005		Yes	No
<a href="#">Results article</a>	health-related quality of life results	01/10/2006		Yes	No
<a href="#">Results article</a>	reliability and validity of the Infant and Toddler Quality of Life Questionnaire results	01/04/2007		Yes	No
<a href="#">Protocol article</a>	protocol	15/09/2010		Yes	No
<a href="#">Results article</a>	results	13/03/2014		Yes	No