ISRCTN15790308 https://doi.org/10.1186/ISRCTN15790308

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

Submission date 07/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/12/2009	**Overall study status** Completed	
Last Edited 17/03/2014	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.generationr.nl/

Contact information

Type(s)
Scientific

Contact name
Dr Hein Raat

Contact details
Erasmus MC University Medical Centre Rotterdam
Department of Public Health
P.O. Box 2040
Rotterdam
Netherlands
3000 CA
+31 (0)10 70 44095
h.raat@erasmusmc.nl

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?
Results article	reliability and validity of the Child Health Questionnaire short form results	01/01/2005		Yes	No
Other publications	questionnaire construct validity	01/02/2005		Yes	No
Results article	reliability and validity of health status measurements results	01/04/2005		Yes	No
Results article	preliminary results	01/10/2005		Yes	No
Results article	health-related quality of life results	01/10/2006		Yes	No
Results article	reliability and validity of the Infant and Toddler Quality of Life Questionnaire results	01/04/2007		Yes	No
Protocol article	protocol	15/09/2010		Yes	No
Results article	results	13/03/2014		Yes	No