The Generation R Study, Phase 3 - Focus at 9

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON41521

Source
ToetsingOnline

Brief title
The Generation R Study, Phase 3 - Focus at 9

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Psychiatric and behavioural symptoms NEC
- Lifestyle issues

Synonym
no specific disorder: growth and development

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: Birth Cohort, Development, Growth, Health

Outcome measures

Primary outcome

The datacollection is divided into several outcomes:

- asthma

- bacterial carriage and infectious disease

- bone density

- cognition

- ethnic and social-economic health inequalities

- behaviour

- growth, overweight and obesity

- neural development

- quality of life

- body composition

- stress reactivity

- risk factors for cardiovasculair disease in children

- risk factors for cardiovasculair disease in women

- musculo-skeletale developement

- circadian rhythm

- physical activity

- sleep

Secondary outcome

not applicable

Study description

Background summary

The Generation R Study is a population-based prospective cohort study from fetal life until young adulthood. The study is designed to identify early environmental and genetic causes of normal and abnormal growth, development and health during fetal life, childhood and
adulthood. The study focuses on four primary areas of research: (1) growth and physical development; (2) behavioural and cognitive development; (3) diseases in childhood; and (4) health and healthcare for pregnant women and children. The Study is divided in several phases. In Phase 3 all children and their mothters are followed from 5- 16 years. The Phase 3 - Focus at 9 all children and their mothers are examined around the age of 9/10. Our proposed project is based on available data (behaviour problems and sleep problems at multiple time points, familial regularity, and harsh parenting), and will add new data: actimetry assessments of circadian activity paterns, and epigenetic profiling across multiple circadian clock genes.

Study objective

The general aim of the Generation R Study is to examine environmental and genetic causes that influence growth, development and health during fetal life, childhood and adulthood.

The more specific aims of the study are:
(1) To describe normal and abnormal growth, development and health from fetal life until young adulthood;
(2) To identify biological, environmental and social determinants of normal and abnormal growth, development and health from fetal life
until young adulthood;
(3) To develop and evaluate strategies for prevention and early identification of groups at risk.

Study design

During Phase 3 of the Generation R study children and their mothers will be examined every three years. The measurements centered around the age of 5 years have been performed from 2008-2012 and recently finished. The Phase 3 - Focus at 9 visit is aimed at children and their mothers around 9/10 years of age. After this the participants will be invited around 13 and 16 years of age. The visits at the research center will take around 2.5 hours. Furthermore, the parents of the children will receive 1 or 2 questionnaires a year focused on behaviour, development, life style habits and circumstances of the child. Finally, based on information from the questionnaires, medical information

about the child will be collected from general practioners, medical specialists, pharmacies and community health centers. Additional to study diurnal rhythm, children wear an actigaphy watch for 9 days.

During the Focus at 9 visit several measurements on the children and their mothers are performed:
* Allergological exam ;
* Ultrasound measurements;
* Dual Energy X Absorptiometry (Dexa) measurements (total body, left hand);
* Behavioural research;
* Hearing measurements;
* Exam of the face and jaw development;
* Physical Exam;
* Pulmonary exam;
MRI exam;
* Motor function exam;
* Retinal exam;
* Dental exam;
* Visus exam;
* Dexa right hip, spinal cord;
Peripheral Quantitative Computed Tomography (pQCT) proximale tibia;
Mechanography/jumping plate exam;
Actigraphy exam;

Study burden and risks

The burden of participation in the Generation R Study will be on average 1.25 hours a year for the child and the mother.
There are no risks related to participation in the Generation R Study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Pariticipation in Generation R Phase 3
Consent for participation in Generation R Phase 3

Exclusion criteria

Temporary or fully withdrawn from participating in the Generation R Study
Death of the child

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2012
Enrollment:	29000
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-07-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL40020.078.12