

Generation R Phase 4 - Focus at Teenagers

Published: 09-02-2016

Last updated: 27-12-2024

Generation R is a population based prospective cohort study. The specific aims of the study are:1) To describe normal and abnormal growth, development and health from early fetal life until young adulthood in a multi-ethnic population;2) To identify...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55374

Source

ToetsingOnline

Brief title

Generation R Phase 4 - Focus at Teenagers

Condition

- Other condition

Synonym

no specific disorder; growth and development

Health condition

Observationele cohortstudie die zich richt op groei, ontwikkeling en gezondheid vanaf het vroege foetale leven tot de jong volwassenheid. Er wordt een breed scala aan factoren en uitkomsten bestudeerd.

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;deelprojecten/onderzoekers worden gefinancierd door (wetenschappelijke) fondsen ,deelprojecten/onderzoekers worden gefinancierd door (wetenschappelijke) fondsen

Intervention

Keyword: Birth Cohort, Development, Growth, Health

Outcome measures

Primary outcome

The study focuses on six areas of research: (1) maternal health; (2) growth and physical development; (3) behavioural and cognitive development; (4) respiratory health and allergies; (5) diseases in childhood; and (6) health and healthcare for children and their parents. In Generation R - Focus at

Teenagers several measurements are performed:

- Dual Energy X Absorptiometry (DXA) measurements
- ECG measurements;
- Ultrasound measurements;
- EEG measurements;
- Endothelial function measurements;
- Eye-tracking measurements;
- Behavior and cognition research;
- Hearing measurements;
- Face and jaw development;
- Skin measurements;
- Biological samples;

- Physical examination;
- Pulmonary examination;
- Gait analyses;
- Mechanography research;
- Collection of medical information;
- MRI scanning;
- Ophthalmologic research;
- Peripheral Quantitative Computed Tomography (pQCT);
- Collection of school information;
- Sleep/actigraphy;
- Spectrophotometry;
- Muscle strength;
- Questionnaires.

Secondary outcome

NA

Study description

Background summary

Generation R studies growth, development and health of children from early pregnancy until adulthood. Ultimately, this research should contribute to the development of strategies to optimize the health and health care for pregnant women and their children.

Study objective

Generation R is a population based prospective cohort study. The specific aims of the study are:

- 1) To describe normal and abnormal growth, development and health from early fetal life until young adulthood in a multi-ethnic population;
- 2) To identify (epi) genetic, biological, social and environmental determinants of normal and abnormal growth, development and health;
- 3) To support the development of strategies for prevention and early identification of groups at risk.

Study design

Generation R is a large-scale multidisciplinary population-based observational cohort study in Rotterdam

Study burden and risks

Based on the NFU table from the *Monitoringplan t.b.v. WMO-plichtig investigator initiated onderzoek*, we consider the Generation R Study to be a study with negligible risk. There are no interventions. There are minimally invasive procedures, but these only carry a very small risk. The radiation exposure is low.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molenwaterplein 50
Rotterdam 3015 GE
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molenwaterplein 50
Rotterdam 3015 GE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Inclusion criteria

Participation in Generation R Phase 1, Consent for participation in Generation R Phase 4

Exclusion criteria

Temporary or full withdrawal 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: Recruiting

Start date (anticipated): 04-04-2016

Enrollment: 29000

Type: Actual

Ethics review

Approved WMO

Date: 09-02-2016

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	26-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	24-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	07-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	07-06-2024
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

CCMO

ID

NL55105.078.15