

Generation R Next

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

Summary

ID

NL-OMON55407

Source

ToetsingOnline

Brief title

Generation R Next

Condition

- Other condition

Synonym

growth and development, no specific disorder

Health condition

Observationele cohortstudie die richt op groei, ontwikkeling en gezondheid vanaf de preconceptionele of 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, Horizon2020

Intervention

Keyword: Birth cohort, Growth & development, Health, Pregnancy

Outcome measures

Primary outcome

Generation R Next focuses on six areas of research: (1) Health of (future) parents; (2) fertility and reproduction; (3) growth and physical development of the child; (4) behavioral and cognitive development of the child; (5) asthma, allergy and infectious diseases of the child; and (6) utilization of healthcare. In Generation R Next - Preconception, pregnancy and early childhood, several measurements are performed:

- Physical examination;
- Body composition examination;
- Heart and vascularization examination;
- Pulmonary examination;
- Gynaecological ultrasound examination;
- Muscle strength examination;
- Face and jaw development;
- Ophthalmologic research;
- Behavior and cognition research;
- MRI examination;

- Biological samples;
- Collection of medical information;
- Questionnaires.

Secondary outcome

NA

Study description

Background summary

The current Generation R study (MEC 198.782/2001/31, MEC 217.595/2002/202, MEC-2007-413; NL21545.078.08, MEC-2012-165; NL40020.078.12 en MEC 2015-749; NL55105.078.15), a population based prospective cohort study, started recruiting pregnant women in December 2001 to study growth, development and health of children born in Rotterdam. Children have been followed from pregnancy onwards and will be followed until adulthood. Extensive experience has been gained in studying (pregnant) women, their partners and children in a multidisciplinary, observational, prospective manner. The study has been resulting in many new insights in maternal and children's health, growth and development; New knowledge raises new research questions. Health and disease in childhood and adulthood seems to be partly determined in early (embryonic) life. The pre- and peri-conception phase, the period around the start of new life, seems to be a critical phase for health in later life. To gain more insight in these critical periods of life and the mechanisms of early exposures underlying health outcomes in later life, we aim to expand the current Generation R study with a new cohort; Generation R Next. We will enroll women prior to conception and focus on preconception and embryonic phases in which exposures, embryonic and early fetal development and placental development will be measured repeatedly. Similar to the current Generation R cohort, a follow-up study of the children and their parents will be performed in the postnatal phase.

Study objective

Generation R Next is a population based, prospective cohort study, focusing on (future) parents with a wish to conceive, and expecting to be parents. By starting the study in the preconception phase we aim to identify determinants of fertility and observe how (epi)genetic, biological, social and environmental determinants influence reproduction, embryonic and fetal growth and development. The children will be followed until young adulthood. Ultimately,

the aim is to support the development of strategies for prevention and optimization of healthcare for future parents, expecting to be parents and their children.

Study design

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

Study burden and risks

The Generation R Next study is an observational medical-scientific study. There are no interventions. There are minimally invasive procedures, but these carry a negligible risk for participants.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Women who want to become pregnant and living in Rotterdam, and their partners;
- Pregnant women and living in Rotterdam, and their partners;
- Consent for participation in Generation R Next.

Exclusion criteria

- Women who, before or during pregnancy, move to somewhere outside Rotterdam;
- Temporarily or full withdrawal from participating in Generation R Next.

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): 09-08-2017

Enrollment: 10000

Type: Actual

Ethics review

Approved WMO

Date: 09-12-2016

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Approved WMO

Date: 07-09-2018

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 31-01-2020

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 11-09-2020

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 12-01-2021

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 11-05-2021

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 24-09-2021

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 17-12-2021

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

ID: 28841

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL57828.078.16
OMON	NL-OMON28841