

Subclinical and clinical disease, transmission, and risk factors of SARS-CoV-2 among children and their families: a household study within the Generation R Study

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a) To determine the occurrence of subclinical and clinical disease and transmission of SARS-CoV-2 in families with children aged 14-18 years; and b) to examine the associations of socio-demographic and lifestyle, genetic, and epigenetic factors with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON49423

Source

ToetsingOnline

Brief title

Generation R CoKids Study

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym

corona virus, COVID-19

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: child, comorbidity, risk factors, SARS-CoV-2

Outcome measures

Primary outcome

SARS-CoV-2 symptoms, infection, severity of disease and transmission, and environmental and genetic risk factors for (sub-)clinical disease and disease severity.

Secondary outcome

NA

Study description

Background summary

The SARS-CoV-2 pandemic is a threat to the health and wellbeing of children and parents. The causes and contributing factors to this are unknown, as is the role of asymptomatic and symptomatic children in the spread of the virus and the development of herd immunity. The Ministry of Health, Welfare and Sport and ZonMw have approached a number of research groups to help answer questions related to the spread and transmission of the virus in specific groups. The UMCU/Spaarne Gasthuis and Erasmus MC in collaboration with the RIVM will study children in various age ranges, who are participating in ongoing cohort studies, to examine carriership and transmission in children and families. Given the impact and relevance of findings for public health decisions and the funding that Generation R receives from the Ministry, we would like to contribute. Due to its prospective, longitudinal and detailed data collection in a large population and its existing infrastructure, the Generation R Study represents an excellent basis for studies into transmission and risk factors of SARS-CoV-2 in children and their families.

Study objective

a) To determine the occurrence of subclinical and clinical disease and transmission of SARS-CoV-2 in families with children aged 14-18 years; and b) to examine the associations of socio-demographic and lifestyle, genetic, and epigenetic factors with subclinical and clinical disease, and transmission of SARS-CoV-2 within households.

Study design

The project will be embedded in the Generation R Study, a population-based prospective study from early pregnancy onwards. A total of 9,778 pregnant women were included between 2002 and 2006 in Rotterdam. The women, their partners and children are being prospectively followed since then. Detailed data have been collected on the participants in multiple follow-up rounds

Study burden and risks

Participation poses minimal risk only. Data are collected through digital questionnaires, an existing app, and by collection of respiratory swabs, saliva, and capillary blood sampling, which may cause transient discomfort and rarely infection. Participants may see their participation as a valuable contribution to science and potentially to society, but the direct personal benefits of participation are limited.

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

- Participation in the Generation R Study *Focus Cohort*
- Consent to be approached for additional studies as indicated in the most recent informed consent form
- Household family members of the participant in the Generation R Study *Focus Cohort* with consent to be approached for additional studies as indicated in the most recent informed consent form

Exclusion criteria

- None

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):	02-10-2020
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO	
Date:	03-09-2020
Application type:	First submission
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	NL74709.078.20