Humoral responses to SARS-CoV2 in children

Published: 02-04-2020
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Objective: To evaluate the humoral response and estimate the prevalence of antibodies against SARS-CoV2 in children during the COVID-19 outbreak in the Netherlands.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52392

Source
ToetsingOnline

Brief title
COVID KIDS study

Condition

- Viral infectious disorders

Synonym
Coronavirus disease COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting tot Steun Emma Kinderziekenhuis

Intervention

Keyword: antibody, children, SARS CoV2

Outcome measures

Primary outcome

Main study parameters/endpoints: IgG, IgM, IgA and total neutralizing

antibodies against SARS-CoV2 in blood and secretory IgA levels against

SARS-CoV2 in saliva from all participants

Secondary outcome

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Study description

Background summary

Rationale: Coronavirus disease 2019 (COVID-19) first started in China in December 2019 and the outbreak was declared a pandemic by the World Health Organization (WHO) on 11 March 2020. Sero-epidemiological studies can identify patients that have been infected with SARS-CoV2, regardless of the severity of their illness. These studies are needed to provide estimates of herd immunity that are essential for public health policy makers. The antibody response is crucial for preventing viral infections and may also contribute to combat infection. The first seroepidemiological studies in adults in the Netherlands are being initiated, but there is currently no data on immunity in children. Evidence is emerging that while children suffer less severely from COVID-19, they do get infected, can spread the virus, and elicit IgG, IgM, IgA or secretory IgA responses. Differences in the humoral response to SARS-CoV2 in between children and adults may partly explain the difference in disease severity.
Objective: To evaluate the humoral response and estimate the prevalence of antibodies against SARS-CoV2 in children during the COVID-19 outbreak in the Netherlands.

Study objective

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Study design

Study design: Multicenter prospective cohort study,

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
This study is classified as an observational study in subjects under 18 years of age. We will ask additional blood to be collected if the patient has blood tests ordered by the treating physician in routine medical care. The child will not be subjected to additional dermal or vena punctures for this study. Blood can be obtained when the child presents to the emergency department, during hospitalization, or in the outpatient clinic of the participating hospitals. We will ask for an additional 1 ml of blood in children aged 0-1 years, 2 ml in 1-5 year olds, and 5 ml in 5-18 year olds. Simultaneously, a saliva sample with a buccal swab will be sampled. The burden to participate in this study is therefore negligible. Parents/guardians can join their child at all times during the procedure.
The individual study results will be shared with the parents/guardians after finalizing the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

All children younger than 18 years of age that have blood drawn for normal/standard medical care in the emergency room, hospital ward or outpatient clinic of a participating hospital

Exclusion criteria

No written informed consent from parents/ guardians or eligible child older than 12 years of age.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2020
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	02-04-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2021

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27267
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73556.018.20
OMON	NL-OMON27267