Humoral responses to SARS-CoV-2 infection in children

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27267

Source
Nationaal Trial Register

Brief title
COVID KIDS study

Health condition

SARS-CoV in children

Sponsors and support

Primary sponsor: Stichting Steun Emma
Source(s) of monetary or material Support: Foundation Contribute

Intervention

Outcome measures

Primary outcome

At the end of the study (april 2021) we will assess the following primary outcomes
Blood :
Neutralizing antibodies (via neutralization assay)
IgG and IgM against SARS-CoV2 (via ELISA)
Saliva:

Secretory total IgA and specific secretory IgA against SARS-CoV2 (via ELISA)

Secondary outcome

NA

Study description

Background summary

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 circulatory and mucosal antibody responses against SARS-CoV2 in children during the COVID-19 outbreak in the Netherlands.

Study design: Multicenter prospective cohort study

Study population: Children younger than 18 years of age in whom blood is drawn for routine medical care in one of the participating hospitals are eligible for participation.

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

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.

Study objective

Children will show circulatory and mucosal antibody responses against SARS-CoV2 even when not having experienced clinical symptoms of COVID19.

Study design

Blood :
Neutralizing antibodies (IgG, IgA and IgM) : via neutralization assay.
IgG and IgM against SARS-CoV2: via ELISA
Saliva:
Secretory total IgA and specific secretory IgA against SARS-CoV2: via ELISA.

All these measurements will be performed between september 2020 and january 2021

Intervention

NA

Contacts

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Eligibility criteria

Inclusion criteria

Children younger than 18 years of age

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
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2020
Enrollment:	420
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-04-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52392
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8531
CCMO	NL73556.018.20
OMON	NL-OMON52392

Study results