Humoral responses to SARS-CoV-2 infection in children

Gepubliceerd: 08-04-2020 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27267

Bron
Nationaal Trial Register

Verkorte titel
COVID KIDS study

Aandoening

SARS-CoV in children

Ondersteuning

Primaire sponsor: Stichting Steun Emma
Overige ondersteuning: Foundation Contribute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Dasja Pajkrt

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Wetenschappelijk

Amsterdam UMC, location AMC
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children younger than 18 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-04-2020
Aantal proefpersonen:	420
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52392
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten