Clinical features of COVID-19 in Pediatric Patients, long term effects

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By means of questionnaires about respiratory symptoms and quality of life, pulmonary function tests and exhaled breath profiles it is possible to to determine pulmonary morbidity in the follow-up of COVID-19 in children

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

Samenvatting

ID

NL-OMON27723

Bron
Nationaal Trial Register

Verkorte titel
COPP2-study

Aandoening

Covid-19 in children

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- To describe potential pulmonary sequelae, in particular symptoms, the need for hospital care, at 6 to 12-months following a COVID-19 diagnosis among pediatric patients receiving

care in the hospital or outpatient setting in the Netherlands.
- To determine risk factors for pulmonary sequelae among COVID-19 hospitalized and outpatient pediatric patients in the Netherlands.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The pandemic novel coronavirus (SARS-COV-2) causes the disease COVID-19, ranging from mild flu like symptoms to severe and potentially fatal acute respiratory distress. In the first case reports of adults who recovered from COVID-19, long term pulmonary sequela are reported. There are currently no long term follow-up data in children.

Objective: We aim to describe the pulmonary characteristics at 6-months following a COVID-19 diagnosis in children seeking care in either the outpatient or hospital setting in the Netherlands.

Study Design: Multi-center descriptive prospective cohort study.

Duration: Following an initial baseline registration as part of the COPP study, children and their caregivers will be requested to return for a follow-up visit 6 to 12 months after diagnosis with COVID-19. We will enroll participants throughout a 1.5 year period.

Study population: Children aged 0 -17 years who were diagnosed in the outpatient department or were hospitalized with COVID-19, and who were included in a previously approved pediatric study, named “clinical features of COVID-19 in pediatric patients” (also known as COPP). In this study, the clinical features, course of disease, response to treatment and risk factors for severe disease in hospitalized and outpatient pediatric patients with COVID-19 in the Netherlands, were described.

Description: Children aged 0 -17 years who were diagnosed with COVID-19 will be recruited from the COPP database if they gave permission to be approached for follow-up studies. Study measurements include: questionnaires and physical examination for all children and exhaled breath and growth measurements, pulmonary function, exercise testing, and Chest CT scans in a subgroup of patients.

Doel van het onderzoek

By means of questionnaires about respiratory symptoms and quality of life, pulmonary function tests and exhaled breath profiles it is possible to to determine pulmonary morbidity in the follow-up of COVID-19 in children

Onderzoeksopzet

All measurements will be performed once during a visit to the outpatient clinic around from 6 to 12 months following a COVID-19 diagnosis, with the exception of the lung CT-scan that will be only performed if applicable under clinical basis during a second visit to the hospital. The procedures during the study visit will depend on the age from the participant and will be performed according to the following:

All ages: Pulmonary symptoms questionnaire
Quality of life questionnaire: TAPQL (0 to 2 years old), PedSQL (older than 2 years), PROMIS (older than 8 years)

Children older than 2 years: exhaled breath analysis (GC-MS)

Children older than 4years: spirometry and exhaled breath analysis (GC-MS, eNose or Spironose)

Children older than 6 years: spirometry, exercise testing and exhaled breath analysis (GC-MS, eNose or Spironose)

Children older than 8 years: spirometry, body plethysmography, exercise testing and exhaled breath analysis (GC-MS, eNose or Spironose)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- Aged 0-17 years at COVID-19 diagnosis, AND
- Presented to an emergency or outpatient department of a Dutch hospital and/or admitted to hospital, AND
- Diagnosed with COVID-19 in his/her medical history, based on at least one positive real-time RT-PCR test on nasopharyngeal, oropharyngeal, sputum or fecal sample for SARS-CoV-2 OR fulfilled a clinical diagnosis of COVID-19, should testing of SARS-CoV-2 yield inconclusive results and/or if testing is no longer possible due to lack of reagents, AND
- Enrolled in the COPP study (Clinical features of COVID-19 in Pediatric Patients (23)), with specific consent to be approached for follow-up studies.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Consent from guardians and/or patient is not received, or
- Consent for COPP study data access is not received

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	120
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:	11-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8926
Ander register	METC AMC : METC 2020_110

Resultaten