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

No registrations found.

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

Summary

ID

NL-OMON27723

Source
Nationaal Trial Register

Brief title
COPP2-study

Health condition

Covid-19 in children

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

- 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.

Secondary outcome

- To describe lung function in the follow-up of children with COVID-19.
- To describe exhaled breath profiles in children with a history of COVID-19
- To assess the quality of life in children with a history of COVID-19.
- To describe CT abnormalities in patients with chronic respiratory complaints and/or pulmonary function test abnormalities and a history of COVID-19.

Study description

Background summary

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.

Study objective

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

Study design

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)

Contacts

Public
Amsterdam UMC, locatie AMC
Caroline Kosterink-Brackel

+31 20 5669111
Scientific
Amsterdam UMC, locatie AMC
Caroline Kosterink-Brackel

+31 20 5669111

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-09-2020
Application type:	First submission

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
NTR-new	NL8926
Other	METC AMC : METC 2020_110

Study results