Post-COVID Complaints in children Study (POCOS)

Published: 26-07-2021
Last updated: 17-01-2025

We aim to describe the clinical characteristics and immune response in children seeking care for post-COVID complaints. Moreover, in a subset of children we evaluate the effect of the reinfection on clinical and inflammatory outcomes in children...

Ethical review	Approved WMO
Status	Completed
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON56078

Source
ToetsingOnline

Brief title
Post-COVID in children (POCOS)

Condition

- Immune disorders NEC
- Viral infectious disorders
- Respiratory tract infections

Synonym
post-COVID syndrome, SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,subsidie-aanvragen lopen nog

Intervention

Keyword: Children, Post-COVID

Outcome measures

Primary outcome

• To describe sequelae of COVID-19, primarily the PROMIS paediatric fatigue score and frequency, duration and intensity of other persisting symptoms

Secondary outcome

• To identify risk factors of increased fatigue (according to PROMIS paediatric fatigue) in children with post-COVID, such as gender, age, ethnicity, pre-existing diseases*

• Functional testing (including spirometry, bodybox, CO-diffusion, exercise tolerance test) and imaging (chest CT-scan and ultrasound and/or MRI of the heart) *

• Blood test abnormalities (kidney, liver function, thyroid function, anaemia, leucocytosis or leukopenia, thrombocytosis or thrombocythemia, increased inflammatory values of erythrocyte sedimentation rate and C-reactive protein) *

• Measures of neurocognitive behavioural, school functioning (patients > 6 years) the Emma toolbox (in the Dutch cohort only)

• PROMIS measures of physical, mental and social health and PedsQL

• Exhaled breath profiles (Dutch cohort only)

• Prevalence of olfactory dysfunction (Dutch cohort only)

• Nasopharyngeal and gastro-intestinal microbiome profiles

• Phenotypic and functional aspects of the innate and adaptive immune system related to the autoimmunity and antibody response against COVID-19

• Immunological profiles in children with post-COVID syndrome, compared to adults (P4O2 Covid-19 Extension study (NL74701.018.20))

• Change in PROMIS paediatric fatigue score before and after reinfection with SARS-CoV-2

• Immunological profiles in children with post-COVID syndrome, compared before and after reinfection with SARS-CoV-2

• Gene-expression profiles (transcriptomics) related to disease phenotypes and severity of post-COVID syndrome

The data needed for the outcomes marked with an * will be retrieved from patient files as they are part of the normal standard of care for children with complaints of long-term fatigue.

Study description

Background summary

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 and cardiogenic shock syndrome. In adults who recovered from COVID-19, long-term sequela (long-COVID/post-COVID/Post-Acute Sequelae of COVID-19 (PASC)) are frequently reported, causing mild to severe long term morbidity. In adults, post-COVID is a well-documented multisystem disease that describes the 10% of COVID-19 infected with long-term sequelae persisting for more than 12 weeks. Far less is known about these long-term sequelae in children, as only recently this disease has started to garner scientific literary attention. In children, the first cohort studies show long term sequelae in 12-42% of patients. A Dutch survey among pediatricians showed 89 children with long term complaints, resulting in severe limitations in daily life in 36%.

Study objective

We aim to describe the clinical characteristics and immune response in children seeking care for post-COVID complaints. Moreover, in a subset of children we

evaluate the effect of the reinfection on clinical and inflammatory outcomes in children with Post-COVID syndrome.

Study design

A mixed-method multi-centre international prospective cohort study, with a feasibility phase and a definitive design phase comprehending 2 possible trajectories:
- Trajectory 1: One study visit to the outpatient clinic and evaluations of quality of life and symptoms (through digital questionnaires sent by email) at 6 and 12 months.
- Trajectory 2: In addition to the trajectory 1, the subgroup of children participating in the evaluation of SARS-CoV2 virus re-infections for Post-COVID syndrome will receive follow-up study visits (or home self-tests) at 3, 6 and 9 months. Moreover, the children also receive extra evaluation moments (self-testing at home) in case of complaints that fit a possible corona infection

Study burden and risks

The results from this study will benefit the target group, i.e. children with post-COVID syndrome, with possible long-term morbidity, leading to early detection and hopefully treatment.
The study visit will be combined with routine standard of care visits to the outpatient clinic or planned in another moment according to the patient*s convenience. Caregivers and/or children will be asked for consent to have data from these outpatient visits retrieved from the hospital file and registered at the study CRF. The procedures which are solely part of research are immunological evaluation, exhaled breath analysis, microbiome analysis, fatigue questionnaires, the neurocognitive questionaires and evaluation tests (Emma Tool box) and an odour identification test.
The exhaled breath and the odour identification test do not provide extra burden to the patient. The administration of the tests included in the Emma toolbox require 30 minutes and could be tiresome for the children. For this purpose we propose the mixed-method design such that after the inclusion of the first 20 patients there will be a re-evaluation to optimize the study procedures according to the expertise acquired in this first (feasibility) phase.
The collection of a nasal and throat swabs provide a minimal burden to the children. Children have reported an itchy feeling and tearing eyes, and in rare circumstances local bleeding might occur.
All children and/or their caregivers will be asked for consent to have additional blood collected for immunological evaluation. Blood withdrawal is standard care in these patients, so the collection of the blood sample for immunological evaluation will be combined with a blood sample collection for routine clinical care.

The expected required time-investment of the children and their caregivers exclusively for the study is approximately 2 hours, depending on the age and willingness of the child. Both the clinical disease-course and the capacity to recover are different in children when compared to adults and we therefore cannot deduce long-term sequelae from adults COVID studies.
Children participating in the reinfection sub-set longitudinal portion of the study will have three additional study visits (home visits or self-sampling) at 3, 6 and 9 months after inclusion. During these visits blood is drawn and questionnaires are administered. Moreover, the children also receive extra evaluation moments (self-testing at home) in the event of complaints that match a possible corona infection. The estimated extra time for the complete reinfection sub-study will be of 2 hours, including all planned study visits.
Participants participating in the extension of trajectory 2, will be followed up for additional 6 months. During these months, participants will continue collecting NP/OP swabs. One additional blood collection and questionnaire is implemeted at april 2024.

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)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Children aged 0-17 years evaluated for post COVID syndrome at one of the participating hospitals and with a history of SARS-CoV-2 infection (RT-PCR test or positive serology or suitable medical history)

Exclusion criteria

-Medical history that (partially) explains the fatigue complaints or chronic fatigue syndrome related complaints in the medical history
- No consent from guardians and/or patient.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-11-2021
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	30-11-2023
Application type:	Amendment
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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
CCMO	NL77824.018.21