Clinical features of COVID-19 in Pediatric Patients (COPP-study)

First published: 16/04/2020

Last updated: 14/03/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/34744

EU PAS number

EUPAS34743

Study ID

34744

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

Rationale: The pandemic novel coronavirus (SARS-CoV-2) causes the disease COVID-19, ranging from mild flu-like symptom to a severe and potentially fatal acute respiratory illness. Data on clinical features and risk factors in children are limited.Objective: We aim to describe clinical features of COVID-19 in children. Study design: Multicenter prospective cohort study. Study population: Children age 0-17 years, in- or outpatient in Dutch hospitals with COVID-19. Main study parameters/endpoints: The main study parameters are 1) Description of the clinical features and risk factors of COVID-19 in hospitalized and outpatient pediatric patients in the Netherlands. 2) Description of the clinical course of COVID-19 in hospitalized and outpatient pediatric patients. 3) Description of the response to treatment, including supportive care. Secondary parameters are characterization of the host responses to infection and COVID-19 in pediatric patients.

Study status

Planned

Research institutions and networks

Institutions

Leiden University Medical Centre (LUMC)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Radboud university medical center (Radboudumc)

Netherlands

First published: 30/06/2022

Last updated: 21/03/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Amsterdam UMC

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Erasmus Medical Centre Rotterdam

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Last updated: 01/02/2024

Institution

Amsterdam UMC Amsterdam, NL, Radboud UMC Nijmegen, NL, UMC Utrecht Utrecht, NL, Erasmus MC Rotterdam, NL

Networks

SPIN and PEDMED-NL

Contact details

Study institution contact

Emmeline Buddingh

Study contact

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Primary lead investigator

Emmeline Buddingh

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2020

Study start date
Planned: 06/04/2020

Date of final study report
Planned: 06/04/2022

Sources of funding

- Other

More details on funding

yet to be determined

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The main study parameters are 1) Description of the clinical features and risk factors of COVID-19 in hospitalized and outpatient pediatric patients in the Netherlands. 2) Description of the clinical course of COVID-19 in hospitalized and outpatient pediatric patients. 3) Description of the response to treatment, including supportive care.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Pharmacokinetic study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

CHLOROQUINE

Medical condition to be studied

Coronavirus infection

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

100

Study design details

Outcomes

Description of the clinical features of the COVID-19 in hospitalized and outpatient pediatric patients in the Netherlands.Description of the clinical

course of the COVID-19 in hospitalized and outpatient pediatric patients.Description of the response to treatment, including supportive care. Characterization of the host responses (inflammatory parameters) to infection and COVID-19 in pediatric patients.Determine cytokine levels (e.g. IL-6) and medication concentrations (e.g. chloroquine) in scarce material.

Data analysis plan

For real-time reporting of anonymous data on the website R will be used (R Foundation for Statistical Computing, Vienna, Austria). IBM SPSS Statistics software (SPSS Statistics for Windows, IBM, Armonk, NY) will be used.Demographic and clinical characteristics will be described using standard statistical analysis methods. The descriptive data will be presented as percentages and medians ± interquartile range, or numbers with percentages.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No