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

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# Administrative details

EU PAS number	
EUPAS34743	
Study ID	
Study ID	
34744	
DADWIN FILE chiede	
DARWIN EU® study	
No	
Chudu countries	
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

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Institution

Universit	y Medical	Center	Utrecht	(UMCU)
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□ Netherlands

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Institution Educational Institution Hospital/Clinic/Other health care facility

ENCEPP partner



# **Amsterdam UMC**

First published: 01/02/2024

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Institution

**Educational Institution** 

Hospital/Clinic/Other health care facility

### **Erasmus Medical Centre Rotterdam**

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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** 

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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

www.covidkids.nl

# Methodological aspects

# Study type

#### 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

# 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)</li>
- 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

#### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

#### 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

# Unknown Check completeness Unknown

#### **Check stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No