

# Investigating the COVID-19 mucosal immunity of children in Indonesia

<b>Submission date</b> 01/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 02/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 01/10/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

The SARS-CoV-2 pandemic has had a profound effect on the lives of all people. Children are a group that gets a lot of attention due to the possibility of subclinical infection and virus transmission. More in-depth knowledge is needed about the development of mucosal immunity (the immune system associated with mucosal sites such as the gut). The aim of this study is to Investigate the COVID-19 mucosal immunity of children in Indonesia.

### Who can participate?

Children aged under 18

### What does the study involve?

Mucosal lining fluid will be taken from participants' noses using sterile filter paper to identify mucosal antibodies towards the SARS-CoV-2 virus. The sample will be collected three times on days 0, 14, and 28. The researchers will also take a medical history from the participants/parents /carers and physically examine the children.

What are the possible benefits and risks of participating?  
There is no risk or benefit from participating.

Where is the study run from?  
Diponegoro University (Indonesia)

When is the study starting, and how long is it expected to run for?  
May 2020 to October 2021

Who is funding the study?  
Diponegoro University (Indonesia)

Who is the main contact?  
Dr Vincentia Rizke Ciptaningtyas  
ciptaningtyas\_vr@fk.undip.ac.id

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Vincentia Rizke Ciptaningtyas

**ORCID ID**  
<http://orcid.org/0000-0001-5910-4937>

**Contact details**  
Diponegoro University Faculty of Medicine  
Jl. Prof. Soedarto SH  
Kelurahan Tembalang  
Kecamatan Tembalang  
Semarang  
Indonesia  
50275  
+62 (0)81325755503  
ciptaningtyas\_vr@fk.undip.ac.id

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
MICIn210920

# Study information

## Scientific Title

SARS-CoV-2 mucosal immunity of children in Indonesia (MICIn study)

## Acronym

MICIn

## Study objectives

The SARS-CoV-2 pandemic has had a profound effect on the lives of all people. Children are a group that gets a lot of attention related to the possibility of subclinical infection, and also the possibility of them transmitting the virus. More in-depth knowledge is needed about the development of mucosal immunity.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 31/08/2020, Diponegoro University Faculty of Medicine Health Research Ethics Committee (Kantor Dekanat Lama FK Undip lt.1, Jl. Dr. Soetomo 18, Semarang, Indonesia; +62 (0) 24 769280010 ext 7820; komisietik@gmail.com), ref: 211/EC/KEPK/FK UNDIP/VIII/2020

## Study design

Community-based monocenter prospective cohort exploratory study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Community

## Study type(s)

Diagnostic

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

COVID-19 (SARS-CoV-2 infection)

## Interventions

All participants will receive the three-time intervention after they have given their consent /assent. The researchers will take a medical history from participants/parents/carer and physically examine the children. Mucosal lining fluid will be collected using sterile filter paper in the nasal cavity to identify mucosal antibodies towards SARS-CoV-2. The sample will be collected three times on days 0, 14, and 28.

## **Intervention Type**

Other

## **Primary outcome measure**

Mucosal immunity of SARS-COV-2 measured using fluorescent-bead-based multiplex immunoassay at baseline, 14 and 28 days

## **Secondary outcome measures**

Disease symptoms measured using physical examination and anamnesis (COVID-19-related symptoms 14 days before sample collection, contact history, and comorbidities), recorded at baseline, 14, and 28 days.

## **Overall study start date**

01/05/2020

## **Completion date**

15/10/2021

## **Eligibility**

### **Key inclusion criteria**

Children aged under 18

### **Participant type(s)**

All

### **Age group**

Child

### **Upper age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

100

### **Key exclusion criteria**

Children without parent/legal guardian permission

### **Date of first enrolment**

15/10/2020

### **Date of final enrolment**

15/12/2020

## **Locations**

## **Countries of recruitment**

Indonesia

## **Study participating centre**

### **Diponegoro University**

Jl. Prof. Soedarto SH  
Kelurahan Tembalang  
Kecamatan Tembalang  
Semarang  
Indonesia  
50275

## **Sponsor information**

### **Organisation**

Diponegoro University

### **Sponsor details**

Jl. Prof. Soedarto SH  
Kelurahan Tembalang  
Kecamatan Tembalang  
Semarang  
Indonesia  
50275  
+62 (0)24 76928010  
dean@fk.undip.ac.id

### **Sponsor type**

University/education

### **Website**

<http://www.undip.ac.id/>

### **ROR**

<https://ror.org/056bjta22>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

## Results and Publications

### **Publication and dissemination plan**

The findings from this research study will be published in an appropriate scientific journal (and made available open access) and/or presented at an appropriate meeting.

### **Intention to publish date**

15/12/2021

### **Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date.

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date