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Investigating the COVID-19 mucosal immunity of children in Indonesia

Submission date
01/10/2020

Recruitment status
No longer recruiting

Registration date
02/10/2020

Overall study status
Completed

Last Edited
01/10/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
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.

Completion date
15/10/2021

Eligibility

Key inclusion criteria
Children aged under 18

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

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
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50275

Sponsor information

Organisation
Diponegoro University

ROR
https://ror.org/056bjta22

Funder(s)

Funder type
University/education

Funder Name
Diponegoro University

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes