

# Investigating pneumonia in children under 5 years of age in Indonesia

<b>Submission date</b> 09/12/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/04/2020	<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

Even though identification and treatment has improved, pneumonia (inflammation and swelling of the lungs often caused by an infection) is the leading cause of death in children worldwide, with approximately 1 million deaths each year. Indonesia has a high rate of pneumonia in children, with 1 in 5 children aged under 5 years suffering from pneumonia each year. This study aims to observe children aged under 5 years in Indonesia who have pneumonia to investigate the type of infection that has caused it, the antibiotics that can kill the bacteria involved and the risk factors that make a child more likely to have pneumonia. The results are expected to help with planning treatment and vaccine use.

### Who can participate?

Children aged under 5 years who have a cough or difficulty breathing and have fast breathing, as long as the first sign of illness was less than 14 days previously.

### What does the study involve?

Children suspected of having pneumonia will be identified at community health centres in different parts of Indonesia. They will have blood samples taken as part of the study and will have their throat and nose swabbed so that bacteria and viruses can be identified. The parents will be asked questions to identify potential risk factors using a questionnaire.

### What are the possible benefits and risks of participating?

This is an observational study, which means that the participants receive treatment as usual. There is no risk or benefit of participating.

### Where is the study run from?

Diponegoro University (Indonesia)

### When is the study starting and how long is it expected to run for?

October 2019 to October 2023

### Who is funding the study?

Diponegoro University (Indonesia)

Who is the main contact?

Dr Vincentia Rizke Ciptaningtyas, [ciptaningtyas\\_vr@fk.undip.ac.id](mailto:ciptaningtyas_vr@fk.undip.ac.id)

### Study website

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

RIDA261119

## **Study information**

**Scientific Title**

Investigation of the modifiable risk factors and etiology of lower respiratory tract infections of children under five years of age in Indonesia

**Acronym**

RIDA

**Study objectives**

A better understanding of the etiology, risk factors and antimicrobial resistance patterns among children with lower respiratory tract infection (LRTI) will improve the healthcare for these patients in Indonesia. Hence, reducing childhood morbidity and mortality caused by LRTI and thereby supporting the third 'sustainable development goal'.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 04/12/2019, Diponegoro University Faculty of Medicine Health Research Ethics Committee (Kantor Dekanat Lama FK Undip Lt.1, Jl. Dr. Soetomo 18, Semarang, Indonesia; +62 024-769280010 ext 7820; komisietik@gmail.com), ref: 506/EC/KEPK/FK UNDIP/XII/2019

**Study design**

Multicentre observational (longitudinal case-control) study

**Primary study design**

Observational

**Secondary study design**

Case-control study

**Study setting(s)**

Community

**Study type(s)**

Diagnostic

**Participant information sheet**

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

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

Lower respiratory tract infection among children aged under 5 years

### **Interventions**

This study is designed as a case control study, whereby cases will be matched with controls (matched by age, sex, time of admission ). Cases will be identified at community health center (Puskesmas) and controls will be enrolled by post for integrated services (Posyandu) where the community health center is located.

All participants will receive a one-time intervention immediately after they have given their consent. The researchers will take a medical history from the parent or carer and physically examine the children, including pulse oximetry. Nasopharyngeal swab, oropharyngeal swab and peripheral vein (blood and serum) will be taken. Information about risk factors will be obtained through a questionnaire designed specifically for this study. Questions in our questionnaire relate to caregiver socio-demographic information (specifically level of education and salary), participant socio-demographic information (specifically antenatal care, breastfeeding and previous illness), immunization status, home-related factors and tobacco exposure.

### **Intervention Type**

Other

### **Primary outcome measure**

Etiology (with a primary focus on bacteria and viruses) of LRTI identified using conventional (bacterial culture) and molecular methods.

### **Secondary outcome measures**

1. Risk factors assessed using parents' and guardians' responses to a questionnaire
2. Antimicrobial sensitivity patterns of isolated bacterial pathogens
3. Virus identification using multiplex PCR
4. Pneumococcal serotypes causing pneumonia identified using multiplex PCR and the Quellung reaction

### **Overall study start date**

01/10/2019

### **Completion date**

01/10/2022

## **Eligibility**

### **Key inclusion criteria**

1. Cough or difficulty in breathing
2. Fast breathing:
  - 2.1. In children aged 2 to 11 months, with breathing rate  $\geq 50$  breaths per min
  - 2.2. In children aged 12 to 59 months, with breathing rate  $\geq 40$  breaths per min
3. First symptom appearing within the last 14 days
4. Aged under 5 years

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

2 Months

**Upper age limit**

59 Months

**Sex**

Both

**Target number of participants**

450

**Key exclusion criteria**

1. Hospitalized for more than 24 h at enrolment
2. Cancer or history of cancer
3. History of long-term (more than 2 months) exposure to steroid drugs

**Date of first enrolment**

01/06/2020

**Date of final enrolment**

01/10/2022

**Locations****Countries of recruitment**

Indonesia

**Study participating centre**

Universitas Diponegoro

Jl. Prof. Soedarto SH

Kelurahan Tembalang

Kecamatan Tembalang

Semarang

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**Sponsor information**

**Organisation**

Universitas Diponegoro [Diponegoro University]

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.undip.ac.id/language/id/>

**Funder(s)****Funder type**

University/education

**Funder Name**

Universitas Diponegoro

**Alternative Name(s)**

undip, Universitas Diponegoro (UNDIP, Universitas Diponegoro (UNDIP) (Semarang, Indonesia), Universitas Diponegoro (UNDIP) Semarang, UNIVERSITAS DIPONEGORO The Excellent Research University, Diponegoro University, UNDIP

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Indonesia

**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**

01/10/2023

**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