

Investigating pneumonia in children under 5 years of age in Indonesia

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

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Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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; komisetik@gmail.com), ref: 506/EC/KEPK/FK UNDIP/XII/2019

Study design

Multicentre observational (longitudinal case-control) study

Primary study design

Observational

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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 ≥ 50 breaths per min
 - 2.2. In children aged 12 to 59 months, with breathing rate ≥ 40 breaths per min
3. First symptom appearing within the last 14 days
4. Aged under 5 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 months

Upper age limit

59 months

Sex

All

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

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50275

Sponsor information

Organisation

Universitas Diponegoro [Diponegoro University]

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

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