ISRCTN79204992 https://doi.org/10.1186/ISRCTN79204992

Investigating pneumonia in children under 5 years of age in Indonesia

Submission date 09/12/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/12/2019	**Overall study status** Completed	
Last Edited 09/04/2020	**Condition category** Infections and Infestations	

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

Study website
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Contact information

Type(s)
Scientific

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Type(s)
Public

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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 ≥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

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
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Sponsor information

Organisation
Universitas Diponegoro [Diponegoro University]

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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