

Common causes and patient outcomes of community-acquired pneumonia in sub-Saharan Africa

Submission date 14/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/01/2022	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/10/2024	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Pneumonia is swelling (inflammation) of the tissue in one or both lungs. It's usually caused by a bacterial infection. Pneumonia is a common cause of death globally and requires appropriate antibiotic treatment. However most of the treatment for pneumonia remains empirical since the tests to establish the causes are not routinely done and these tests may not be able to detect the germs causing disease in a large percentage of patients with pneumonia. With widespread use of antibiotics for treating pneumonia, some of the germs causing pneumonia infection may be resistant to commonly used antibiotics and this may lead to poor treatment response among patients with pneumonia. This study uses novel tests for pneumonia to investigate whether they improve the diagnosis of pneumonia and help to identify germs that are resistant to usual antibiotics. Secondly, it investigates whether additional tests may help to identify patients with pneumonia who are at risk of poor response to treatment

Who can participate?

Adult patients diagnosed with pneumonia.

What does the study involve?

Patients will provide a sputum sample for analysis.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Infectious Disease Institute (Uganda)

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

February 2020 to September 2024

Who is funding the study?

European & Developing Countries Clinical Trials Partnership (EDCTP) (South Africa)

Who is the main contact?
Dr William Worodria, worodria@yahoo.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Management of Lower Respiratory Tract Infections in Sub-Saharan Africa, a pragmatic approach

Acronym
LoRTISA

Study objectives
1. Adding nucleic acid testing for viruses and other hard to detect pathogens will improve microbiological identification of pathogens by at least 33%
2. Blood biomarkers like CRP and PCT may be useful clinically and help to identify individuals with pneumonia at risk of early treatment failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 17/11/2020, Makerere College of Health Sciences, School of Medicine, Research Ethics Committee (PO Box 7072, Kampala, Uganda; +256 414533541; ponsiano.ocama@gmail.com), ref: 2020-204

Study design

Observational single centre cohort study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Community acquired pneumonia

Interventions

Patients hospitalized with community acquired pneumonia will have their sputum tested using conventional culture based tests and this will be compared with multiplex PCR tests to determine the performance of these novel molecular diagnostic tests for pneumonia. Clinical biomarkers (C-reactive pneumonia and procalcitonin) will also be used to assess the prognosis of patients with pneumonia.

Intervention Type

Mixed

Primary outcome(s)

Diagnostic test (Biofire FilArray) compared with the gold standard at study enrollment

Key secondary outcome(s)

Biomarkers (CRP, PCT) compared against Early Treatment failure at day 3 using sputum test

Completion date

30/09/2024

Eligibility

Key inclusion criteria

1. Clinically diagnosed pneumonia (fever $\geq 38^{\circ}\text{C}$, with cough, chest pain, breathlessness or hemoptysis) and at least one focal chest sign (crepitations, pleural rub, bronchial breathing, dullness on percussion or diminished breath sounds) for <3 weeks
2. Consent to study participation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Hospitalized in the last 30 days
2. Cancer chemotherapy
3. Have chronic renal failure
4. Treatment for active pulmonary tuberculosis
5. Respiratory failure secondary to severe chronic obstructive lung disease
6. Congestive heart failure

Date of first enrolment

18/01/2022

Date of final enrolment

30/08/2024

Locations

Countries of recruitment

Uganda

Study participating centre

Infectious Disease Institute

P.O. Box 22418

Kampala

Uganda

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Sponsor information

Organisation

Infectious Diseases Institute

ROR

<https://ror.org/02caa0269>

Funder(s)

Funder type

Government

Funder Name

European and Developing Countries Clinical Trials Partnership

Alternative Name(s)

Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaio Clínicos, The European & Developing Countries Clinical Trials Partnership (EDCTP), The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes