ISRCTN61173943 https://doi.org/10.1186/ISRCTN61173943

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

Submission date
14/12/2021

Recruitment status
No longer recruiting

Registration date
31/01/2022

Overall study status
Completed

Last Edited
14/10/2024

Condition category
Infections and Infestations

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

Study website
https://idi.mak.ac.ug/edctp/dr-william-worodria/

Contact information

Type(s)
Scientific

Contact name
Dr William Worodria

ORCID ID
http://orcid.org/0000-0002-8531-5567

Contact details
Infectious Diseases Institute
P.O. Box 22418
Kampala
Uganda
-
+256 772424601
wworodria@idi.co.ug

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

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

Overall study start date
01/02/2020

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Clinically diagnosed pneumonia (fever ≥38°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

Age group
Adult

Sex
Both

Target number of participants
406

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
-

Sponsor information

Organisation
Infectious Diseases Institute

Sponsor details
P.O. Box 22418
Kampala
Uganda
-
+256-31-2211422
samong@idi.co.ug

Sponsor type
Research organisation

Website
https://idi.mak.ac.ug/

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 Ensaios Clínicos, 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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/11/2024

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