ISRCTN33572982 https://doi.org/10.1186/ISRCTN33572982

Addressing the challenges associated with neglected infectious diseases in at-risk individuals

Submission date
06/09/2021

Recruitment status
No longer recruiting

Registration date
17/11/2021

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
This study seeks to establish the relevance of opportunistic fungal co-infections with the specific aims of:
1. Determining the burden of fungal co-infections among patients with chronic pulmonary (lung) disease suspected of tuberculosis (TB)
2. To establish and characterise microbial communities associated with chronic pulmonary disease
3. To characterise potential interactions between fungal and bacterial communities

Who can participate?
Patients aged 18 and over with a productive cough presenting with TB-like symptoms

What does the study involve?
Three sputum samples will be collected from each participant with a space of 3-4 days for analysis of the incidence of pulmonary fungal infections.

What are the possible benefits and risks of participating?
Possible benefits include improved diagnosis and management of patients. No risks are foreseen.

Where is the study run from?
Mbarara University Teaching Hospital (Uganda)

When is the study starting and how long is it expected to run for?
October 2020 to September 2024

Who is funding the study?
European & Developing Countries Clinical Trials Partnership (Netherlands)

Who is the main contact?
Dr Herbert Itabangi
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TMA2019CDF-2789-MeMoF

Study information

Scientific Title
Metabolic and molecular ecological evolution of opportunistic pulmonary fungal co-infections

Acronym
MUREC-1/7

Study objectives
1. The burden of opportunistic pulmonary fungal co-infections is higher than culture-dependent data suggests
2. Culture-independent data complements culture-dependent data in supporting therapeutic decisions
3. Fungal-bacterial co-existence influences fungal virulence

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/10/2020, Mbarara University of Science and Technology Research Ethics Committee (PO Box 1410, Mbarara, Uganda; +256 (0)485433795; sec.rec@must.ac.ug, irc@must.ac.ug), ref: MUREC1/7

Study design
Laboratory-based cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pulmonary fungal co-infections in patients with TB-like symptoms

Interventions
Participants earmarked for the study will be consented to, instructed and guided on the sputum sample collection. Up to three samples will be collected from each participant with a space of 3-4 days. Following collection, the samples will be examined for some preliminary results that can be used in the management of participants. Following complete sample collection, the participants will not be required again and thus no follow up will be required.

Intervention Type
Other

Primary outcome(s)
Incidence of pulmonary fungal infections measured using Prevalence Index at baseline and 18, 30 and 36 months

Key secondary outcome(s))
Clinical management measured using a diagnostic approach at baseline and 36 months

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. HIV/AIDS patients suspected of TB
2. Presenting with TB-like symptoms including a chronic cough that has persisted for more than 3 months
3. Aged 18 years and above
4. TB naive
5. Give consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Critically ill patients, who would delay recruitment due to associated delays in sample collection and consent
2. Diabetics and pregnant women suspected of TB are managed differently according to TB guidelines
3. HIV/AIDs patients with TB-like symptoms but on anti-TB treatment
4. Patients with a known diagnosis

Date of first enrolment
10/10/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Uganda

Study participating centre
Mbarara University of Science and Technology, Teaching Hospital
PO Box 1410
Mbarara
Uganda
256

Study participating centre
Busitema University Teaching Hospital
PO Box 1460
Mbale
Uganda
256

Sponsor information

Organisation
Mbarara University of Science and Technology

ROR
https://ror.org/01bkn5154

Funder(s)

Funder type
Research organisation

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 (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 datasets generated during and/or analysed during the current study are/will be available upon request from Dr Herbert Itabangi (hitabangi@gmail.com/hitabanngi@must.ac.ug). Data will be shared as required by the WHO and ICMJE.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/08/2023	16/08/2023	Yes	No
Participant information sheet			09/09/2021	No	Yes
Preprint results		05/12/2023	25/11/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes