

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

<b>Submission date</b> 06/09/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/01/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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  
hitabangi@must.ac.ug

**Study website**  
<http://www.must.ac.ug>

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Herbert Itabangi

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

See additional files

**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 measure**

Incidence of pulmonary fungal infections measured using Prevalence Index at baseline and 18, 30 and 36 months

**Secondary outcome measures**

Clinical management measured using a diagnostic approach at baseline and 36 months

**Overall study start date**

01/10/2020

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

480

**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

**Sponsor details**

PO Box 1410

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Uganda

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+256 782 199188

us@must.ac.ug

**Sponsor type**

Research organisation

**Website**

<https://www.must.ac.ug>

**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, 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**

Findings to be published in high-impact journals with open access.

**Intention to publish date**

01/10/2022

**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?
<a href="#">Participant information sheet</a>			09/09/2021	No	Yes
<a href="#">Protocol article</a>		15/08/2023	16/08/2023	Yes	No
<a href="#">Preprint results</a>		05/12/2023	25/11/2024	No	No