

The burden of serious fungal diseases in Uganda

Submission date 27/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/02/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Information is limited on the magnitude of the burden of serious fungal diseases in Uganda. Serious fungal diseases that can potentially lead to death include infections in the blood or internal organs. This study investigates blood fungal diseases and mycetoma, which commonly affects the foot. The study aims to describe the number of people with the disease, risk factors for acquiring the disease and environmental sources (if any) of the fungi causing the disease. Additionally, the study will be focused on determining the environmental sources of *Cryptococcus*, which causes disease in the blood.

Who can participate?

Two categories of people can participate in the study:

1. Sick people who have signs of blood fungal infection, including fever for a long time which fails to respond to the common antibiotics, having high breathing and heart rates and low blood pressure when brought to the hospital
2. People who have a large, non-painful swelling, commonly on the foot, which is draining some fluids and perhaps some grains

What does the study involve?

The study involves three activities:

1. Collection of blood from sick people to study the number and risk factors and the type of medicine for people with fungi.
2. Collection of muscle tissue from patients with mycetoma of the foot to study the fungi causing it.
3. Collection of samples from the environment- such as tree barks to determine the environmental sources of *Cryptococcus* species.

What are the possible benefits and risks of participating?

Possible benefits include a guided treatment plan which includes timely laboratory results and information on incidental findings. Risk factors include the patients becoming anaemic from loss of blood (8-10 ml) which is significant in critically ill patients. However, the likelihood of a positive blood culture increases with a higher blood volume. Blood draws will be made in consultation with the attending clinicians at the study sites. Other risk factors include secondary wound infection during sample collection for the study of mycetoma. Patients who get secondary bacterial infections will be supported to access the standard of care.

Where is the study run from?
Makerere University (Uganda)

When is the study starting and how long is it expected to run for?
November 2019 to October 2022

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

Who is the main contact?
Dr Beatrice Achan
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Study website
<https://chs.mak.ac.ug/content/epidemiology-invasive-fungal-diseases-uganda>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2021-000459-38

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
The epidemiology of invasive fungal diseases in Uganda

Acronym
Fungal-UG

Study objectives
There is limited information on the epidemiology of invasive fungal diseases in Uganda. Therefore, the study aims to describe the epidemiology of invasive fungal diseases in Uganda.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 23/07/2020, Makerere University School of Biomedical Sciences Research and Ethics Committee (PO Box 7072 Kampala, Uganda; +256 (0)752 575 050; biomedicalresearch62@gmail.com), ref: SBS639
2. Approved 23/03/2020, Uganda National Council for Science and Technology (Uganda National Council for Science and Technology, PO Box 6884, Kampala, Uganda; +256 (0)414 705 500; info@uncst.go.ug), ref: HS2610

Study design
Descriptive cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

<https://www.fungal-ug.com/>

Health condition(s) or problem(s) studied

Fungal bloodstream infections, mycetoma

Interventions

Blood culture retrieved fungi will be identified to the species level by a phenotypic algorithm for identification; the India ink, Germ tube test, use of 10% KOH, culture on/in identification media and EUCAST method will be used for antifungal susceptibility testing.

Intervention Type

Other

Primary outcome measure

1. The number of patients with fungal bloodstream infections measured using blood culture specimens collected at baseline (enrolment)
2. The number of patients with mycetoma measured by histopathological stains on biopsy specimens collected at baseline (enrolment)
3. The environmental distribution of *Cryptococcus* species causing cryptococcal meningitis using PCR of environmental samples at baseline

Secondary outcome measures

1. Species of fungal pathogens isolated, identified using the conventional phenotypic algorithm for identification after blood culture at 7 days
2. Antifungal resistance profile of fungal pathogens isolated, measured using EUCAST method at 48 h per protocol
3. Molecular ecology of *Cryptococcus* measured using PCR assay at 48 h

Overall study start date

01/11/2019

Completion date

31/10/2022

Eligibility**Key inclusion criteria**

1. Adults aged >18 years with features of sepsis: temperature >38, tachycardia, tachypnoea, suspected focus of infection
2. Adults aged >18 years with features of mycetoma: painless subcutaneous mass, multiple sinuses, discharge

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

N = 385 with sepsis, N= 177 with mycetoma

Key exclusion criteria

Patients who do not provide informed consent

Date of first enrolment

01/03/2020

Date of final enrolment

01/07/2022

Locations

Countries of recruitment

Uganda

Study participating centre

Mulago National Referral Hospital

Kampala

Uganda

-

Study participating centre

Lacor Hospital

Gulu

Uganda

-

Study participating centre

Lira Regional Referral Hospital

Lira

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Sponsor information

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Sponsor type

University/education

Website

<https://chs.mak.ac.ug/content/epidemiology-invasive-fungal-diseases-uganda>

ROR

<https://ror.org/03dmz0111>

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 Ensaaios 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 open access peer-reviewed journals.

Intention to publish date

01/11/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available online repository called Fungal-UG database that will be made available at manuscript submission for 1 year. The information will be open access for sharing with the global community. Consent for further research is included in the consent forms, approved by the ethical review committees. All data will be anonymised using only study identification numbers. The database is currently not yet online for purposes of protecting the data set before publication.

IPD sharing plan summary

Stored in repository