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The burden of serious fungal diseases in Uganda

Submission date
27/01/2021

Recruitment status
No longer recruiting

Registration date
05/02/2021

Overall study status
Completed

Last Edited
05/02/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
bachan@chs.mak.ac.ug

Contact information

Type(s)
Scientific

Contact name
Dr Beatrice Achan

ORCID ID
https://orcid.org/0000-0001-9741-5429

Contact details
Department of Medical Microbiology
Room C22
Upper Mulago Hill Road
Kampala, Uganda
Kampala
Uganda
-
+256 (0)784 260 263
bachan@chs.mak.ac.ug

Type(s)
Public

Contact name
Mr Joseph Odokonyero Odokonyero

ORCID ID
https://orcid.org/0000-0001-9741-5429

Contact details
Mycobacteriology Laboratory
Kampala
Uganda

+256
+256 (0)782 593 959
odokonyero.joseph@chs.mak.ac.ug

Additional identifiers

Clinical Trials Information System (CTIS)
2021-000459-38

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Uganda
-

Sponsor information

Organisation
Makerere University

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 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes