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Improvement in cryptococcosis diagnosis among HIV-infected patients in Mozambique

Submission date
04/08/2024

Recruitment status
Recruiting

Registration date
06/08/2024

Overall study status
Ongoing

Last Edited
27/05/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Laboratory diagnosis for cryptococcal disease among HIV-infected patients remains a challenge in most low- and middle-income countries (LMIC). Difficulties with sustained access to cryptococcal rapid tests are cited as a major barrier to the routine screening for cryptococcus in many LMICs. Thus, clinicians in these countries often resort to empirical treatment based solely on clinical suspicion of cryptococcosis. To address this challenge, this study aims to evaluate the re-introduction of India ink microscopy testing for the diagnosis of cryptococcosis among HIV-infected patients in southern Mozambique. India ink testing was historically a common first choice, low-cost, laboratory diagnostic tool for cryptococcal infection.

Who can participate?
Clinicians attending adult HIV-infected patients in screening or consultation rooms and laboratory technicians

What does the study involve?
This study involves a multicenter study that will employ a mixed-methods approach, guided by an implementation science framework the Dynamic Adaptation Process (DAP). It will be carried out in three phases (pre-implementation, implementation, and post-implementation). The intervention will be rolled out in six hospitals using a stepped-wedge trial approach. Using a modified RE-AIM, the study will assess the intervention’s implementation at two levels: individual (healthcare providers) and organizational (hospitals and their healthcare system).

What are the possible benefits and risks of participating?
Possible benefits of participating include increasing the opportunity for screening cryptococcosis among HIV-infected patients and making available an etiologic diagnosis to reduce empirical treatment practices among clinicians. The intervention is deemed of negligible risk because a diagnostic tool that offers no risk to healthcare providers is being re-introduced.

Where is the study run from?
University Eduardo Mondlane (Mozambique)

When is the study starting and how long is it expected to run for?
December 2022 to July 2026

Who is funding the study?
Fogarty International Center (USA)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Re-introduction of India ink microscopy testing as a low-cost laboratory diagnostic for cryptococcosis among HIV-infected patients in Southern Mozambique: An implementation research protocol

Study objectives

The re-introduction of a low-cost laboratory diagnostic for cryptococcoses HIV-infected patients in Southern Mozambique can improve the diagnoses of cryptococcoses in the intervention sites

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/10/2023, National Bioethics Committee for Health of Mozambique (Ministry of Health, 2nd Floor, Avenue Eduardo Mondlane, Salvador Allende, Maputo, 00000, Mozambique; +258 824066350; cnbsmocambique@gmail.com), ref: 622/CNBS/23

Study design
Multicenter stepped-wedge implementation science trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Laboratory

Study type(s)
Diagnostic, Screening

Participant information sheet

Health condition(s) or problem(s) studied
Re-introduction of India ink microscopy testing as a low-cost laboratory diagnostic for cryptococcosis among HIV-infected patients

Interventions
Following completion of the pre-implementation phase assessments and local stakeholder adaptation meetings, each study facility will roll out India Ink microscopy for cryptococcosis diagnosis as per the stepped-wedge design. Upon initiation of implementation, HIV care clinicians will identify suspected cryptococcosis patients based on clinical suspicion. Urine will be requested and submitted to the laboratory on the same day for microscopy testing using India Ink. Once at the laboratory, the urine sample will be analyzed by laboratory technicians trained in the diagnosis of cryptococcosis by the study, and to standardize the procedures they will follow the India Ink microscopy technique on urine samples SOP (Standard Operating Procedure) provided in all the laboratories of the study.
The results will be available on the same day and be transferred from the laboratory back to the clinician through the sample and information flow adapted in this study to enhance the interaction between clinicians and laboratory staff.

Intervention Type
Other

Primary outcome measure

Increase opportunity for screening of adult HIV-infected patients suspected of having a cryptococcal disease in study sites measured using microscopy testing with India Ink at one time point

Secondary outcome measures
1. Empirical treatment practice time among clinicians managing cryptococcal infections measured using record keeping during the sample and information flow
2. Clinician satisfaction with the availability of the tool for clinical decision support measured using an in-depth interview record and a 5-point Likert scale at 9 months of the adaptation-intervention period (the end of the intervention phase)

Overall study start date
15/12/2022

Completion date
31/07/2026

Eligibility

Key inclusion criteria
Healthcare providers: clinicians attending adult HIV-infected patients in screening or consultation rooms and laboratory technicians

Participant type(s)
Health professional

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
98 healthcare providers (67 clinicians and 31 laboratory technicians)

Key exclusion criteria
1. Clinicians attending to pediatric patients
2. Clinicians who are not engaged in HIV/AIDS care and treatment
3. Laboratory technicians who are not engaged in laboratory diagnostic testing for cryptococcosis

Date of first enrolment
01/09/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Mozambique

Study participating centre
Maputo Central Hospital
Maputo
Mozambique
0000

Study participating centre
Mavalane General Hospital
Maputo
Mozambique
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Study participating centre
Jose Macamo General Hospital
Maputo
Mozambique
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Study participating centre
Matola Provincial Hospital
Matola
Mozambique
0000

Study participating centre
Xai-Xai Provincial Hospital
Xai-Xai
Mozambique
0000

Study participating centre
Carmelo Hospital of Chokwe
Chokwe
Mozambique
0000

Sponsor information

Organisation
Tulane University

Sponsor details
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United States of America
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Sponsor type
University/education

Website
https://sph.tulane.edu/

ROR
https://ror.org/04vmvtb21

Funder(s)

Funder type
Research organisation

Funder Name
Fogarty International Center

Alternative Name(s)
Fogarty, Fogarty at NIH, John E. Fogarty International Center, John Edward Fogarty International Center, NIH John F. Fogarty International Center, NIH's Fogarty International Center, NIH Fogarty International Center, Fogarty International Center at NIH, Fogarty International Center, U.S. National Institutes of Health (NIH), Fogarty International Center AT THE NATIONAL INSTITUTES OF HEALTH, FIC

Funding Body Type

Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Publication and dissemination plan
At the study's end, the investigators will prepare a written report for submission to the Mozambican Ministry of Health as well as a manuscript and presentations of results to be submitted to the peer-reviewed literature and for presentation at international and domestic scientific conferences.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The de-identified datasets generated during and/or analyzed during the current study will be stored in a publicly available repository at https://osf.io./r2kw4. Consent from participants was required and will be obtained. An original consent form is attached to this registration. Participants will be de-identified through codes. All identifying information will be kept locked in a file at the Faculty of Medicine of Eduardo Mondlane University in Maputo.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 04	04/10/2023	06/08/2024	No	Yes
Protocol file		11/10/2023	06/08/2024	No	No
Protocol article		23/05/2025	27/05/2025	Yes	No