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Hidden transmission routes and attitudes towards sleeping sickness in Nigeria

Submission date	Recruitment status	[_] Prospectively registered
09/10/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2024	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and Study Aims
Human African Trypanosomiasis (HAT) is a parasitic disease that can present as either acute or chronic disease. In Nigeria, where this study is based, the species of parasite that is present is called Trypanosoma brucei gambiense, which typically causes chronic disease and can be present in an infected person for a long period of time with little or no obvious symptoms. This study aims to investigate the extent to which local people in the population of Nigeria are acting as silent carriers (people who are asymptomatic) of sleeping sickness by carrying the disease for a long time. This study will look for instances where both parents and their children are infected following possible transmission from mother to child. The study will also find out what knowledge and experience locals and policymakers have regarding HAT in their daily lives or their professional experience.

Who can participate?
Healthy volunteers aged between 1 and 100 years old who have previously taken part in screening for HAT, as well as their family members. Additionally, people involved with policymaking will be contacted for participation in interviews.

What does the study involve?
The study involves the screening of local people who have previously taken part in screening for HAT and their family members. This will include blood sampling by finger prick for Card Agglutination Trypanosomiasis Test (CATT) and PCR tests to identify exposure to HAT and/or active infection. There will also be a semi-structured questionnaire/focus group discussion aspect to the study to explore attitudes and knowledge. Policymakers will be interviewed, but will not participate in blood sampling.

What are the possible benefits and risks of participating?
Possible benefits of participating include bringing the risks of disease to the participant's attention, they could learn information about the prevention of sleeping sickness and what the signs or symptoms are.

Risks include minor pain to the tip of the finger, swelling and possible discolouration of the skin that should clear within a couple of days after sampling.

Where is the study run from?
The University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
March 2023 to March 2024

Who is funding the study?
The University of Edinburgh - Zhejiang University Joint Institute (UK)

Who is the main contact?
Ms Caitlin Jones, s1324273@ed.ac.uk (UK)
Dr Ayodele Majekodunmi, ayo.majekodunmi@ed.ac.uk (UK)
Prof Susan Welburn, sue.welburn@ed.ac.uk (UK)

Contact information

Type(s)
Principal investigator

Contact name
Miss Caitlin Jones

Contact details
1 George Square
Edinburgh
United Kingdom
EH8 9JZ
+44 (0)131 650 8301
s1324273@ed.ac.uk

Type(s)
Scientific

Contact name
Prof Susan Welburn

Contact details
1 George Square
Edinburgh
United Kingdom
EH8 9JZ
+44 (0)131 650 8301
sue.welburn@ed.ac.uk

Type(s)
Public

Contact name
Dr Ayodele Majekodunmi

Contact details
1 George Square
Edinburgh
United Kingdom
EH8 9JZ
+44 (0)131 650 8301
ayo.majekodunmi@ed.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AC23088, NHREC/01/01/2007-15/07/2019

Study information

Scientific Title
Contribution of maternal transmission and silent carriers in the epidemiology and persistence of African trypanosomiasis in human populations

Study objectives
The hypothesis is that asymptomatic carriers and the occurrence of maternal transmission contributes in maintaining foci of Trypanosoma gambiense in Nigeria

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/04/2023, National Health Research Ethics Committee of Nigeria (NHREC) (Department of Health Planning, Research & Statistics, Federal Ministry of Health, 11th Floor, Federal Secretariat Complex Phase III, Ahmadu Bello Way, Abuja, -, Nigeria; +234 09 523 8367; deskofficer@nhrec.net), ref: NHREC/01/01/2007- 25/04/2023C

Study design
Cross-sectional cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Attitudes and knowledge of Human African Trypanosomiasis (HAT), and the contribution of silent carriers and maternal transmission of HAT in Nigeria

Interventions

People who have previously had Human African Trypanosomiasis (HAT) will be recruited alongside their family members in their local towns and tested using in-field diagnostics for HAT, as well as blood stored on filter paper to be tested by PCR. They will then answer questions to elucidate attitudes and knowledge of HAT. Additionally, policymakers will be interviewed regarding the impact of COVID-19 on the neglected tropical diseases (NTDs) work in Nigeria.

Intervention 1
Testing of community members for HAT to establish occurrences of HAT and their distribution in the community

Materials include card agglutination tests for trypanosomiasis (CATT), filter paper, finger prick needles, PPE, alcohol swabs and plasters. The procedure will be to take finger prick blood samples from individuals who had a previously positive CATT/PCR test in 2020 and their family members. These samples will be tested in the field with CATT tests as well as stored on filter paper for later PCR testing in the laboratory. Local community healthcare workers and government-trained phlebotomists with phlebotomy and HAT diagnostic training and experience will collect blood samples and perform in-field testing assisted by study investigators. Laboratory testing will be performed by study investigators who have been trained in sample extraction, processing and PCR. The finger pricking and in-field testing will happen individually, face-to-face in community health settings and town halls. The PCR testing will be undertaken in a University of Edinburgh laboratory. Each person will have a single finger prick/testing appointment no repeats will be taken. The laboratory testing will be repeated as necessary to meet the demands of research rigour. This will be taken from the stored samples and so will not require further interaction with the patients. Samples will be stored for a maximum of 2 years after the study. The intervention is in line with existing protocols and guidance from WHO on field and PCR testing for HAT. Tailoring was only performed in the patients recruited by looking at previously positive patients and their families. Modifications, adherence and fidelity of the intervention during the course of the study will be monitored, assessed, documented and improved by the study investigators led by Caitlin Jones.

Intervention 2
Questionnaires for those with a previously positive CATT/PCR test for HAT in 2020 and their families (same study population as the blood testing from intervention 1) to elucidate attitudes and knowledge of HAT

Materials include: paper questionnaires to be answered by participants, and pens. Participants will be issued with a questionnaire after having their blood samples taken. Healthcare workers and study investigators will ask participants questions and document the responses. The questionnaires will be collected, stored, scanned and digitalised in accordance with GDPR and data storage regulations on a secure University of Edinburgh server and physical storage site. Local community healthcare workers and study investigators with knowledge of HAT and working with patients will be on hand to support patients in answering the questionnaires. The questionnaires will happen individually, face-to-face in community health settings and town halls. Each study participant will complete a single questionnaire at their appointment, no repeats will be taken. The questionnaires have been tailored for the study communities. These have been developed by the study investigators based on questionnaire guidance when working in community health settings. Modifications, adherence and fidelity of the intervention during the course of the study will be monitored, assessed, documented and improved by the study investigators led by Caitlin Jones.

Intervention 3
Focus groups for those with a previously positive CATT/PCR test for HAT in 2020 and their families (same study population as the blood testing from intervention 1) to elucidate attitudes and knowledge of HAT.

Materials include preset questions to guide focus group discussions and materials to record the discussion including pens and paper. Participants will be invited to a focus group session after intervention 1 and 2. Focus groups will be given topics and questions to discuss, facilitated by the study investigators. Discussions will be documented, scanned and digitalised in accordance with GDPR and data storage regulations on a secure University of Edinburgh server and physical storage site. Local community healthcare workers and study investigators with knowledge of HAT and working with patients will be on hand to facilitate the focus groups and guide discussion. The focus groups will be face-to-face in groups in community health settings and town halls. Each focus group will occur once and participants will be invited to attend. The focus group-guided questions have been tailored for the study communities. These have been developed by the study investigators based on focus group guidance when working in community health settings. Modifications, adherence and fidelity of the intervention during the course of the study will be monitored, assessed, documented and improved by the study investigators led by Caitlin Jones.

Intervention 4
Key informant/Policymaker interviews to discuss the impact of COVID-19 on the neglected tropical diseases (NTDs) work in Nigeria.

Materials include preset questions designed to guide the discussion and materials to record the discussion including pens and paper and an encrypted recording device. Study investigators will have a discussion with Key informants/Policy makers guided by preset questions. The discussion will be documented, stored and summarised in accordance with GDPR and data storage regulations on a secure University of Edinburgh server. Study investigators with knowledge of neglected diseases work in Nigeria and Covid-19 will undertake the interviews. The interviews will happen individually, face-to-face in public office and Key informants/Policymakers office settings. Individuals wishing to conduct their interview remotely will be interviewed and recorded via Microsoft Teams and their consent will be obtained using Adobe Sign. Each Key informant/Policymaker will be interviewed once, no repeats will be taken. The interviews have been tailored for Key informants/Policymakers in Nigeria. The questions will be a guide to the discussion in the format of a semi-structured questionnaire. Therefore, the interviews will adapt due to the speciality, knowledge and experience of the individual being interviewed. Modifications, adherence and fidelity of the intervention during the course of the study will be monitored, assessed, documented and improved by the study investigators led by Caitlin Jones.

Intervention Type
Other

Primary outcome(s)
Individuals test positive or negative for HAT measured using the standard protocols for Card Agglutination Trypanosomiasis Test (CATT) within 24 hours of sample collection or by PCR within 1 year of sample collection

Key secondary outcome(s))
1. Number of asymptomatic carriers assessed by the number of positive individuals with no symptoms measured using CATT within 24 hours of sample collection or PCR within 1 year of

sample collection
2. Maternal transmission cannot be assured but suspected if multiple family members test positive measured using CATT within 24 hours of sample collection or PCR within 1 year of sample collection
3. Attitudes and knowledge of HAT measured using a questionnaire and focus group on the same day as sample collection
4. Knowledge of the impact of COVID-19 on neglected tropical diseases in Nigeria ascertained by interview of policymakers at baseline

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Willing and able to provide written informed consent
2. Individuals aged 18 years and above and residing in the study area for the questionnaire aspect of the study
3. Individuals over the age of 1 years old and residing in the study area for the blood sampling aspect of the study
4. Previously tested positive or are related to primary case from prior study
5. Key Informants which will include Ministerial officials, local government policymakers, non-governmental organizations, WHO or FAO representatives in Nigeria, and key academic research contacts

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
All

Lower age limit
1 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Unwillingness or unable to provide consent
2. Failure to establish relatedness primary case
3. Individuals aged less than 18 years for the questionnaire aspect of the study
4. Individuals less than 1 years old for the blood sampling aspect of the study

Date of first enrolment

01/11/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
United Kingdom

Nigeria

Study participating centre
Federal Ministry of Health Nigeria
M3 Federal Secretariat Complex
Phase III
Shehu Shagari Way
Central Business District
Abuja
Nigeria
P,M.B 083 Garki

Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
University/education

Funder Name
University of Edinburgh

Alternative Name(s)
Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Zhejiang University

Alternative Name(s)
Chekiang University, Chekiang Higher Institutes, National Third Chungshan University, National Chekiang University, Zheda, Qiushi Academy, , , ZJU, NCKU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

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