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Trypanocide resistance and opportunities in the era of the COVID-19 pandemic in East Africa

Submission date 10/04/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [X] Individual participant data
Registration date 23/05/2022	**Overall study status** Completed	
Last Edited 19/01/2024	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims

Liberalization of the pharmaceutical industry in several developing countries has increased farmers' access to trypanocides (veterinary drugs) without seeking prescriptions from veterinarians, enabling farmers to rely on indigenous knowledge thus raising major global health challenges. Treatments and dosages are influenced by the farmers' personal knowledge, consultations with friends and learning through trial and error while using trypanocides. A great disregard for professional consultations has led to resistance to trypanocides, especially diminazene aceturate and isometamidium chloride which are massively abused.

Individual farmers’ sentiments don’t necessarily influence the adoption of pharmacovigilance (drug safety) approaches to minimize the threat of trypanocide resistance. Perceived production costs, community superstitious beliefs, miscommunication, and adverse side effects are major barriers faced in rural communities of Africa. Common practices are increased farmer supervised vector control methods, bush burning and acaricide use, practices which raise major public health concerns of drug toxicity and environmental pollution. These practices have also been associated with enormous farm economic losses, making livestock production very unproductive. The continued lack of routine strategic national trypanocide monitoring infrastructure in several developing countries has led to the emergency of resistant trypanosomes in healthy communities. Fake trypanocides smuggled into the country and unlicensed unprofessional animal attendants continue to create further confusion in rural communities on how to effectively address trypanocide resistance.

Trypanosomiasis is a zoonotic infection involving wildlife, humans, and livestock with interlocking socioeconomic drivers, necessitating the adoption of a One Health paradigm to address challenges at the community interface. The development of trypanocide resistance implies that the World Health Organization (WHO) 2030 target is threatened should different stakeholders fail to work together. Competing interests from other neglected zoonotic diseases (NZD) in Africa implies there is a competition for capital, demonstrating a need to revise the global health strategy in developing countries. The WHO and World Trade Organization have expressed an interest in supporting studies on trypanocides, although this initiative has been slowed down by the current pandemic. Controlling NZD helps developing countries establish strong inter-multidisciplinary teams which will help them address regional epidemics and the next pandemic better.

Who can participate?
Adults who are engaged in livestock production or COVID control (veterinarians, farmers and veterinary drugshop sellers in Mbarara district, ministerial officials, local government policymakers and key academic research contacts)

What does the study involve?
This will be a questionnaire survey conducted amongst people who interact with livestock species in East Africa.

What are the possible benefits and risks of participating?
None

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

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

Who is funding the study?
1. National Institute for Health Research (UK)
2. Royal Society of Tropical Medicine and Hygiene (UK)
3. Commonwealth Scholarship Commission (UK)

Who is the main contact?
Prof. Sue Welburn
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
AC22065

Study information

Scientific Title
Trypanocide resistance and COVID

Acronym
TrypCOV

Study objectives
Poor pharmacovigilance practices are responsible for the increasing trypanocide resistance in developing countries in an era of the pandemic

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/06/2022, Edinburgh Medical School Research Ethics Committee (EMREC, Welcome Trust Centre for Cell Biology, Michael Swann Building, King's Buildings, Mayfield Road, Edinburgh, EH9 3BF, UK; Tel: not provided; emrec@ed.ac.uk), ref: 22-EMREC-022
2. Approved 14/07/2022, School of Veterinary Medicine and Animal Resources Institutional Animal Care and Use Committee (SVAR IACUC, Makerere University, College of Veterinary Medicine, Animal Resources and Biosecurity, PO Box 7062, Kampala, Uganda; Tel: not provided; svariacuc.irb@gmail.com), ref: SVAR-IACUC/114/2022

Study design
Observational cross sectional study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Antimicrobial resistance

Interventions
This will be done in the Mbarara district of southwestern Uganda. Study areas in Mbarara are Kashari, Rwampara and Biharwe subcounty. This will be done strategically leaving out the city center which has all the veterinary drug pharmacies. In each subcounty, after reading the participant information form (Appendix I and II) and filing in the data consent form (Appendix III), 384 farmers will be chosen and a questionnaire will be administered by the Chief Investigator (Appendix IV-V). In a follow-up survey, a qualitative case study methodology with an inductive thematic approach will be applied in Uganda and Tanzania to help categorize the institutional current level of preparedness to handle the COVID-19 pandemic as previously described (Elton et al., 2021). The study will explore barriers and facilitators to more resilient and sustainable policy, explore policy networks and identify opportunities to strengthen national One Health

coordination mechanisms (A. L. Okello et al., 2014). To assess how and where to apply the One Health in the pandemic control strategies, key informant interviews from the Ministry of Health, Ministry of Agriculture Animal Industry and Fisheries (MAAIF), Ministry of Gender, National Environmental Management Authority (NEMA), Uganda Wildlife Authority (UWA) and Ministry of Justice will be conducted in Uganda and Tanzania.

Intervention Type
Other

Primary outcome(s)
Knowledge of, attitudes towards and practices leading to trypanocide resistance assessed using a questionnaire at a single timepoint

Key secondary outcome(s))
Government policy regarding trypanocide resistance assessed using interviews with policy makers at a single timepoint

Completion date
20/12/2022

Eligibility

Key inclusion criteria
1. Willing and able to provide written informed consent
2. Study 1: veterinarians, farmers and veterinary drugshop sellers in Mbarara district
3. Study 2: ministerial officials, local government policymakers and key academic research contacts

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
570

Key exclusion criteria
Study I:
1. Unwilling or unable to provide written informed consent
2. Conflict of interest i.e., drug company officials and politicians

Study II:
1. Unwillingness to provide consent
2. Failure to establish contact with participants due to unreliable appointments
3. Persons in influential political positions who could offer a biased opinion (e.g., opposition politicians and persons in the community)

Date of first enrolment
20/07/2022

Date of final enrolment
20/12/2022

Locations

Countries of recruitment
Tanzania

Uganda

Study participating centre
University of Edinburgh
Old College
South Bridge
Edinburgh
United Kingdom
EH8 9YL

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Royal Society of Tropical Medicine and Hygiene

Alternative Name(s)
The Royal Society of Tropical Medicine and Hygiene, RSTMH

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Commonwealth Scholarship Commission

Alternative Name(s)
The CSC, Commonwealth Scholarship Commission UK, Commonwealth Scholarship Commission, United Kingdom, CSC

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article		13/12/2023	18/12/2023	Yes	No
Dataset			19/01/2024	No	No