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Palliative care for multi-drug resistant tuberculosis (TB) in Uganda

Submission date
04/08/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Tuberculosis (TB) is a bacterial infection spread through inhaling tiny droplets from the coughs or sneezes of an infected person. It mainly affects the lungs, but it can affect any part of the body, including the tummy (abdomen), glands, bones and nervous system. TB is a potentially serious condition, but it can be cured if it's treated with the right antibiotics. Multi Drug Resistant Tuberculosis (MDR TB) does not respond to the two most powerful anti TB drugs of choice (Rifampicin and Isoniazid)
MDR TB is an emerging issue in Uganda and worldwide. Our study will first work with health care professionals to develop the best way to deliver end of life (palliative) care alongside existing MDR TB care. We will then test this new model of care in an experiment, comparing patients who receive the new model to those who receive existing care, and asking patients to self-report their wellbeing. Finally, we will ask patients who received the new model how they experienced it and how it may have worked.

Who can participate?
People on treatment for MDR TB in three treatment centers of Mulago National Referral Hospital, Gulu Regional Referral Hospital and Mbale Regional Referral Hospital. Participants need to be aged 18 years or over, able to communicate in English, Luganda, Acholi, Lugisu and able to give informed consent.

What does the study involve?
Patients will randomly be allocated to standard care or standard care plus palliative care offered during routine MDR TB care.
Participants will be interviewed monthly for a total of 5 research interviews.
Participants in the intervention group who will have given consent at their first contact will be individually interviewed. MDR TB patients allocated to the control arm of the trial will receive routine MDR TB care delivered by the designated MDR TB nurses who have not received formal palliative care training.

What are the possible benefits and risks of participating?
There are no direct benefits for those taking part in the study. However, this may be an opportunity for patients to learn ways of managing symptoms and concerns experienced due to

MDR TB disease. There are no risks involved to those taking part in the study and every effort will be made not to inconvenience patients.

Where is the study run from?
Mulago National Referral, Mbale Regional Referral, and Gulu Regional Referral Hospitals in Uganda

When is the study starting and how long is it expected to run for?
January 2018 to March 2021

Who is funding the study?
BUILDCare Africa Grant – Kings College London/ Open Society Foundations (UK)

Who is the main contact?
Nasur Buyinza, nbuyinza@hospiceafrica.or.ug

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Nurse-led integrated palliative care for multi drug resistant tuberculosis patients taking anti multi drug resistant TB therapy in Uganda: a randomized controlled trial

Study objectives
Integrated nurse-led palliative care intervention for Multi Drug Resistant TB patients improves patient self-reported outcomes (symptoms and concerns) compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 25/01/2018, King's College London PNM Research Ethics Subcommittee (Frankin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Rd, London, SE1 9NH, UK; +44 (0)207 848 4020; rec@kcl.ac.uk), ref: HR-19/20-14450
2. Approved 01/11/2018, Hospice Africa Uganda Research and Ethics Committee (Hospice Africa Uganda, P.O. Box 7757, Kampala, Uganda; +256 703184199; research@hospiceafrica.or.ug), ref: none provided
3. Approved 03/04/2019, Uganda National Council for Science and Technology (Plot 6 Kimera Road, Kampala, Uganda; +256 414 705500; no email provided), ref: none provided

Study design
Mixed methods randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Multidrug-resistant tuberculosis

Interventions
MDR TB patients who will have been randomly allocated to the intervention group will receive palliative care from palliative care specialist nurses who will receive a two days intensive integrated palliative care training for MDR TB with regular weekly clinical support supervision from an experienced senior palliative care provider. Options to call for support or referral of complex cases to a specialized palliative care unit will be put in place.

Nurses with previous recognized palliative care training will be trained to provide palliative care services to MDR-TB patients under study. Study participants allocated to the intervention group will receive an initial assessment using an integrated assessment form so developed. These will then be physically followed up either on the ward or at home depending on where they will be at the time of follow up; follow up will be done once every week if a participant is still admitted on the ward and every two weeks if they are at home over the three months period of the study. However for every alternative week, at least one phone contact will be made to participants so as to be able to address any issues that may have arisen in between the review periods. For each review appointment, the standard MDR TB care which comprises of an existing MDR TB care for Uganda will be offered in addition to an adapted MDR-TB palliative care package based on the Hospice Africa Uganda Model which integrates facility based care and home visits. This model is in line with the African Palliative Care Association’ standards for providing palliative care which focuses on holistic assessment of the patient and management of psychological, spiritual, physical and social problems. As may be required on a case by case basis, this minimum palliative care package will be supplemented by additional clinical support.

The intervention will consist of 6 palliative care appointments spread over three months; this will take the form of holistic assessment, care and management of physical, psychological, spiritual, and social needs as well as planning for referral of complicated cases to specialised centres.

MDR TB patients allocated to the control arm of the trial will receive routine MDR TB care delivered by the designated MDR TB nurses who have not received formal palliative care training.

Randomisation:
After collection of baseline information about eligible participants, participants are randomly assigned (1:1) to either intervention or control. We generated a simple computer randomisation and stratified by recruiting centres and block randomisation with various sizes: 4, 6, 8,10 and 12. Randomisation was generated at King's College London. The generated randomisation was then sent to PI (Nasur Buyinza) in Uganda who is implementing randomisation with research assistants.

Intervention Type
Mixed

Primary outcome(s)
Self-reported palliative care-related symptoms and concerns (measured using the Integrated APCA African POS) at baseline and then monthly for 4 months

Key secondary outcome(s))
At baseline and then monthly for 4 months:
1. Quality of life assessed using GHQ-12 and the World Health Organization quality of life (WHOQOL - BREF) assessment tool
2. Social support assessed using MOS Social Support Survey
3. Adherence to treatment which will be measured during clinical assessment using the Adherence and Alcohol tool
4. Service use measured with Client Services Receipt Inventory (CSRI)

Completion date
01/03/2021

Eligibility

Key inclusion criteria
1. 18 years and above
2. Diagnosis of MDR TB
3. Registered at the MDR TB clinic of the respective study sites
4. Willing to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
All MDR TB patients attending the respective study sites who are unable to memorize past events due to their impaired cognitive ability as judged by attending physicians and all those who cannot express themselves in English or local language will be excluded from this study.

Date of first enrolment
18/12/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
Uganda

Study participating centre
Mulago National Referral Hospital
Mulago Hill
PO Box 7051
Kampala
Uganda
Box 7051

Study participating centre
Gulu Regional Referral Hospital
Lira Gulu Road
Kampala
Uganda
Q7HX+29

Study participating centre
Mbale Regional Referral Hospital
Pallisa Road

Kampala
Uganda
Box 921

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
BUILDCare Africa Grant

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/05/2025	27/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes