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Hospital versus community management during the intensive phase of the tuberculosis (TB) re-treatment regimen

Submission date
31/05/2013

Recruitment status
No longer recruiting

Registration date
04/06/2013

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Approximately 10% of patients being treated for tuberculosis (TB) each year in Malawi have already received one course of TB treatment. A first episode of TB is treated with a standard course of tablets for six months. For patients who require treatment for a second episode of TB, the World Health Organisation recommends that they should receive tablets for eight months, and also have daily injections of the antibiotic streptomycin for the first two months of the treatment course (this treatment is called re-treatment regimen). Currently, the only way for patients to receive these injections is to be admitted to the hospital for two months. There are many potential disadvantages to these long period of hospital admissions, including financial and social costs to patients and their households, economic costs to health systems, and risks of patients acquiring infections from being in the hospital. The aim of this study is to test whether these patients can be managed in the community rather than in the hospital.

Who can participate?
Any adult, aged 16 years or older, who is being registered to start TB re-treatment regimen at the participating hospitals, can be enrolled into the study.

What does the study involve?
Patients recruited to the study will identify a guardian who, if they are willing, will be trained how to give the injections. During the period when the guardian is being trained, the patient will stay in the hospital. Of the patients whose guardian successfully learns how to give the injections, half will stay in the hospital for 2 months in order to receive the injections, and the other half will go home where their guardian will give them the injections every day. The study team will visit the patients at home every 1 to 2 weeks, and more often if there are any problems. The outcome will be compared. Social and economic factors associated with hospital and community management will also be assessed.

What are the possible benefits and risks of participating?
The possible benefit of participating in the study is that patients and guardians will be able to return home rather than staying in hospital for 2 months. The risks of participating in the study

are mainly those related to unsafe injection of streptomycin by guardians in the home. The main concerns are that the injections could introduce infections if not done in a sterile, germ-free way, or cause damage to nerves supplying the leg if they are given at the wrong position. In order to reduce these risks, thorough training and strict assessments of guardians will be made prior to discharging the patients, so that, only those patients who have a guardian able to safely give injections are sent home.

Where is the study run from?
The study will be run from two central hospitals in Malawi Queen Elizabeth Central Hospital in Blantyre, and Bwaila Hospital in Lilongwe.

When is the study starting and how long is it expected to run for?
The study is starting in June 2013, and it is expected to run for up to 2 years.

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Dr Danielle Cohen
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13.11

Study information

Scientific Title
The TB Re-treatment Regimen: Outcomes and Care Study (TB-RROC): A trial of hospital versus community management during the intensive phase of the TB re-treatment regimen

Acronym
TB-RROC

Study objectives
Community-based management provides a safe and feasible alternative to hospital-based management during the intensive phase of the TB retreatment regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Malawi College of Medicine Research Ethics Committee, Reference number: P.02/13/1340, Date: 17.05.2013
2. Liverpool School of Tropical Medicine Research Ethics Committee, Reference number: 13.11, Date: 22.05.2013

Study design
Pragmatic, individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Community management of patients requiring injectable therapy as part of the TB re-treatment regimen

Interventions
There will be a 2-stage enrolment and recruitment process. In the first stage, all patients starting retreatment regimen will be approached to identify a treatment supporter (guardian) who will be trained in the technique of intramuscular injection. In the second stage, those who are deemed clinically fit for discharge and whose guardian becomes competent at injection

technique will be randomised to receive standard of care (i.e. remain in hospital for the duration of the intensive phase of TB treatment) or to the intervention arm (i.e. to complete the intensive phase of treatment in the community).

Group 1: 134 patients, randomised to receive the intervention. These participants will be discharged home where they will receive daily oral treatment and intramuscular streptomycin injections administered by their trained guardian, until the 2 month course of injections is completed.
Group 2: 134 patients, randomised to receive standard of care. These participants will remain in hospital where they will receive daily oral treatment and intramuscular streptomycin injections administered by nursing staff, until the 2 month course of injections is completed.

Participants will all be reviewed at home or in hospital by the study team at 1, 3, 5 and 7 weeks post randomisation, and more frequently if required. At the end of the 2 month intervention period, all patients will continue to receive TB treatment under routine care and complete the 8 month course of oral TB treatment as per national guidelines.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient still alive and on TB treatment at the end of the two-month intervention period

Secondary outcome measures
1. 2-month culture conversion in those culture positive at baseline
2. 8-month programmatic TB outcome
3. Serious adverse events during the intensive phase of treatment
4. Karnofsky score 1, 3, 5, and 7 weeks post randomisation
5. Mental health status at 2 months using a Chichewa validated self-reporting questionnaire (SRQ)

Overall study start date
10/06/2013

Completion date
10/06/2015

Eligibility

Key inclusion criteria
1. Adults ≥ 16 years of age starting TB re-treatment regimen
2. Patients who are able to give informed consent
3. Patients who are able to identify a suitable treatment supporter

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
268

Total final enrolment
204

Key exclusion criteria
1. Patients identified as having Multi-drug-resistant tuberculosis (MDR-TB) on GXP or drug sensitivity testing using culture (these patients will be referred to the NTP MDR programme)
2. Pregnant women
3. Patients not planning to stay in Blantyre/Lilongwe for the 2-month duration of the intervention
4. Patients unable to give informed consent
5. Patients unable to identify a suitable treatment supporter

Date of first enrolment
10/06/2013

Date of final enrolment
10/06/2015

Locations

Countries of recruitment
Malawi

Study participating centre
Malawi Liverpool Wellcome Clinical Research Programme
Blantyre
Malawi
BT3

Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

Sponsor details
Pembroke Place
Liverpool

England
United Kingdom
L3 5QA

Sponsor type
University/education

Website
http://www.lstmliverpool.ac.uk

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust Reference no: 097466/B/11/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	06/11/2019	Yes	No