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Effectiveness and feasibility of hospital and community-based delivery of care for multi-drug resistant tuberculosis in Pakistan

Submission date
25/01/2012

Recruitment status
No longer recruiting

Registration date
29/03/2012

Overall study status
Completed

Last Edited
17/06/2016

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is a serious bacterial infection that mainly affects the lungs. Multidrug-resistant TB (MDR-TB) is caused by bacteria that are resistant to the two most potent TB drugs. MDR-TB is a global public health threat, with nearly half a million cases of MDR-TB emerging every year, yet in many resource-constrained countries the treatment of MDR-TB is absent or inadequate. The management of MDR-TB is long (18-24 months) and complex as it requires a system of continuing care with multiple challenges. During the hospitalization of MDR-TB patients for the initial “intensive” phase of treatment, infection control measures limit the number of cases that can be simultaneously treated. An early start of community-based care could help resource-constrained programmes to make efficient use of limited resources. The aim of this study is to find out whether community-based care is equally effective, safe, acceptable, and cost-effective for treating MDR-TB patients compared to hospital-based care.

Who can participate?
Adult patients with MDR-TB

What does the study involve?
Patients are randomly allocated to receive either community-based care or hospital-based care. In the community-based group each patient is referred to a clinic near to their place of residence for outpatient care within about 7 days of their initial hospitalization. The initial few days of hospitalisation are important for investigations, prescribing, education, starting treatment and arranging a treatment supporter near the patient’s home. In the hospital-based group each patient is hospitalized initially for about two months, and hospital staff administer daily drugs under supervision. After two months, they are referred to a clinic near to their place of residence for outpatient care. The proportion of patients who are successfully treated (cured and treatment completed) is compared between the two groups.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants, but this study hopes to improve the care of MDR-TB patients in the future. There are no added risks involved in participating in this study.

Whether the patient agrees or not to participate, he/she will have the same tests and treatment. The only difference is how this treatment is given, with earlier or later discharge from hospital to care at home, with visits to the nearby Rural Health Centre for supervised treatment.

Where is the study run from?
The study will run from four main MDR-TB treating hospitals, one each from district Rawalpindi and Multan and two from district Lahore (Pakistan).

When is the study starting and how long is it expected to run for?
July 2011 to December 2016

Who is funding the study?
University of Leeds - COMDIS-HSD (UK)

Who is the main contact?
Dr Muhammad Amir Khan
asd@asd.com.pk

Contact information

Type(s)
Scientific

Contact name
Dr Muhammad Amir Khan

Contact details
Association for Social Development
House No. 12
Street 48, F-7/4
Islamabad
Pakistan
44000
+92 (0)51 2611 231 33
asd@asd.com.pk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSLTLM11013

Study information

Scientific Title

Effectiveness and feasibility of hospital and community-based delivery of care for multi-drug resistant tuberculosis in Pakistan: a randomized controlled trial

Study objectives
The treatment success of at least 55% can be achieved, whether MDR-TB patient is initially hospitalised for a week or for a two-month period, before getting referred for decentralized delivery of multi-drug resistant tuberculosis (MDR-TB) care with continued monthly follow-up visit to the MDR-TB hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, University of Leeds, 12/01/2012, ref: HSLTLM11013

Study design
Pragmatic individually randomized 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
Multi-drug resistant tuberculosis (MDR-TB)

Interventions
In arm 1 (hospitalisation) each patient will be hospitalized for initial about two months, and hospital inpatient staff will administer daily drugs under supervision. After two months, they will be referred to a strengthened DOTS-Plus clinic near to their place of residence for ambulatory care. Two months hospitalisation is suggested on the basis of systematic review and expert clinical and programme opinion.

In arm 2 (community-based) each patient is referred to a strengthened DOTS-Plus clinic near to their place of residence for ambulatory care within about 7 days of initial hospitalization. The initial few days of hospitalisation is important for baseline investigations, prescribing, education and initiating treatment and arranging a treatment supporter near the patients home.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of treatment success (cure and treatment completion rate) of MDR-TB treatment for community-based care as compared to hospital-based care

Secondary outcome measures
1. Intermediary outcomes like sputum and culture conversion will be assessed
2. The feasibility assessment, through economic and qualitative studies, will address both the patients abilities to cope with care requirements (both for hospital-based and community-based options) and the programmes ability to manage the services including cost and quality of care
3. We will include the indicators - such as treatment adherence and reasons for default. We will investigate patient and provider opinion on these issues, including side effects, influencing adherence and outcomes in the qualitative study. However, the drug regimens have already been decided by the decision of the NTP, and are not a focus of this trial.

Overall study start date
01/07/2011

Completion date
31/12/2016

Eligibility

Key inclusion criteria
All sputum positive confirmed adult cases of MDR-TB, of both gender, registered at selected treating hospitals, residents of the same district as that of the strengthened MDR TB DOTS Plus clinics

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
214 patients will be required in each arm (a total of 428 patients)

Key exclusion criteria
1. Patients who require hospitalisation for medical reasons other than MDR-TB, before or after registration, as these patients cannot be randomized
2. Patient belongs to a family from which one patient has already been recruited in the trial
3. Is less than twelve years old and
4. Patient does not consent to participate in the trial

Date of first enrolment
01/07/2011

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
Association for Social Development
Islamabad
Pakistan
44000

Sponsor information

Organisation
University of Leeds - COMDIS-HSD (UK)

Sponsor details
Leeds Institute of Health Sciences
Charles Thackrah Building
101 Clarendon Road
Leeds
England
United Kingdom
LS2 9LJ
-
J.Walley@leeds.ac.uk

Sponsor type
University/education

Website
http://www.leeds.ac.uk/hsphr/research/NCIHD/comdis-hsd.html

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds - COMDIS-HSD (UK)

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