ISRCTN70846313 https://doi.org/10.1186/ISRCTN70846313

Clinical trial of WHO multibacillary multidrug therapy versus rifampicin, moxifloxacin and clarithromycin on multibacillary leprosy patients from India

Submission date
27/06/2024

Recruitment status
No longer recruiting

Registration date
08/07/2024

Overall study status
Completed

Last Edited
19/08/2024

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
This clinical trial focuses on evaluating the effectiveness and safety of a new treatment for leprosy. Leprosy is a chronic infectious disease caused by the bacterium Mycobacterium leprae. The study aims to determine if the new treatment can reduce the bacterial load, achieve a complete clinical cure, and improve pathological (disease) markers in patients with leprosy.

Who can participate?
Patients aged 15-60 years with multibacillary leprosy who have not received treatment

What does the study involve?
Participants will receive the new treatment and undergo various assessments, including tests measuring bacterial load, clinical examinations to assess lesion regression and overall improvement, and tests to evaluate changes in the Bacillary Index (BI). These assessments will occur at the start of the study and after 3 months, 6 months, and 1 year.

What are the possible benefits and risks of participating?
Benefits:
1. Participants may experience improvement in their leprosy symptoms.
2. Contribution to scientific knowledge that may help future patients with leprosy.
Risks:
1. Possible side effects of the treatment, ranging from mild to severe.
2. Regular follow-up visits and tests may be time-consuming.

Where is the study run from?
The Leprosy Mission Trust India

When is the study starting and how long is it expected to run for?
March 2023 to July 2025

Who is funding the study?
Indian Council of Medical Research

Who is the main contact?
Dr Joydeepa Darlong, joydeepa.darlong@leprosymission.in

Contact information

Type(s)
Principal investigator

Contact name
Dr Joydeepa Darlong

ORCID ID
https://orcid.org/0000-0002-3242-8875

Contact details
16, Pandit Pant Marg
CNI Bhavan
New Delhi
India
110001
+91 (0)9434885198
joydeepa.darlong@leprosymission.in

Type(s)
Scientific

Contact name
Dr Itu Singh

ORCID ID
https://orcid.org/0000-0003-0596-8566

Contact details
Stanley Browne Laboratory
TLM Community Hospital Shahdara
Delhi
India
110093
+91 (0)9717730549
itu.singh@leprosymission.in

Type(s)
Public

Contact name
Dr Reeta Devi

ORCID ID
https://orcid.org/0000-0002-4107-4271

Contact details
TLM Community Hospital Shahdara
Nand Nagari
Delhi
India
110093
+91 (0)6006203600
reeta.devi@leprosymission.in

Type(s)
Public

Contact name
Dr Samrun Nessa

Contact details
TLM Community Hospital Shahdara
Delhi
India
110093
+91 (0)9110322091
samrun.nessa@leprosymission.in

Type(s)
Public

Contact name
Dr Neeta Maximus

Contact details
TLM Hospital Barabanki
Barabanki
India
225001
+91 (0)9936566849
neeta.maximus@leprosymission.in

Type(s)
Public

Contact name
Dr Vandana Elkana

Contact details
TLM Chandkhuri
Bilaspur
India
495222

+91 (0)9981774449
vandana.elkana@leprosymission.in

Type(s)
Scientific

Contact name
Dr Utpal Sengupta

ORCID ID
https://orcid.org/0000-0002-1177-1076

Contact details
Stanley Browne Laboratory
TLM Community Hospital Shahdara
Delhi
India
110093
+91 (0)9212761651
utpal.sengupta@leprosymission.in

Type(s)
Scientific

Contact name
Mr Karthikeyan Govindasamy

ORCID ID
https://orcid.org/0000-0001-5500-1308

Contact details
16, Pandit Pant Marg
CNI bhavan
New Delhi
India
100001
+91 (0)9935284315
karthikeyan.g@leprosymission.in

Type(s)
Scientific

Contact name
Dr Anamika Haldar

Contact details
The Leprosy Mission Home and Hospital
Purulia, West Bengal
India

723101
+91 (0)8271855993
anamika.haldar@leprosymission.in

Type(s)
Scientific

Contact name
Dr Ann Miriam Jose

Contact details
Molecular Biology Lab
Schieffelin Institute of Health – Research & Leprosy Centre (SIH-R & LC)
Vellore
India
632106
-
annmjose97@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CTRI/2024/03/064435

Study information

Scientific Title
A comparative multicentric non-inferiority clinical trial of WHO multibacillary multidrug therapy with a new monthly chemotherapy regimen containing rifampicin, moxifloxacin and clarithromycin on multibacillary patients from India

Acronym
RMC

Study objectives
Monthly rifampicin, moxifloxacin and clarithromycin (RMC) are as efficacious and safe as WHO multibacillary multidrug therapy (MBMDT) in patients affected by multibacillary leprosy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/11/2023, TLMTI ethics Committee (16, Pandit Pant Marg, CNI Bhawan, New Delhi, 110001, India; +91 (0)9811912926; monicathomaschandy@gmail.com), ref: TLMTI/EC/C- 68

Study design
Open-label randomized clinical control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Leprosy

Interventions
It is an open-label randomized clinical control non-inferiority trial where in the intervention group a monthly supervised regimen of rifampicin, moxifloxacin and clarithromycin will be administered in doses of 600 mg, 400 mg, and 1000 mg respectively once a month and the control arm would be given routine WHO MB MDT (rifampicin 600 mg, clofazimine 300 mg once monthly and clofazimine 50 and dapsone 100 mg daily). The duration of the treatment in both arms will be 12 months. The random sequence will be generated centrally which will be sent to study centers in opaque envelopes. After consent is approved, the envelope will be opened, and the patient will be put on the respective arms. The study population will include newly diagnosed, previously untreated MB leprosy patients. Written informed consent will be sought from every subject included in the study.

Slit skin smears of all the study subjects will be collected at baseline, 6 and 12 months and transported in RNA later to the SBL. Real-time PCR will be done to quantitate copy numbers of the genes encoding 16S rRNA, hsp18 and exsA specific for M. leprae. Resistance studies will be carried out at 12 months in patients harbouring viable bacilli. Validation of M. leprae growth in mouse foot pad will be performed on participants showing viable load by molecular methods at the time of RFT in Schieffelin Institute of Health – Research and Leprosy Centre Karigiri (SIHR&LC), Vellore.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Rifampicin, moxifloxacin, clarithromycin, clofazimine, dapsone

Primary outcome(s)
1. Molecular:
1.1. Reduction of copy numbers by molecular viability assay (MVA) measured using quantitative PCR (qPCR) at baseline, 1, 3, 6 and 12 months
1.2. Complete killing of M. leprae assessed using mouse foot pad (MFP) assay at release from treatment (RFT) (12 months)
2. Clinical:
2.1. Complete clinical cure, defined as full regression of the lesions, assessed through clinical examination at baseline, 6 months, and 1 year

2.2. Clinical improvement of the lesions measured by a clinical criterion (e.g., lesion size reduction) at baseline, 6 months, and 1 year
3. Pathological:
3.1. Bacillary Index (BI) improvement measured using skin smears and histopathological examination at baseline, 3 months, 6 months, and 1 year

Key secondary outcome(s))
1. Immunological outcomes:
1.1. Neuritis measured through patient self-reporting of pain during interviews and nerve function tests (e.g., sensory and motor function tests) every month during the treatment period and thereafter 6 monthly for 1 year
1.2. Type I reaction assessed through clinical examination and patient reporting with type 1 reaction from the development of the reaction to its subsidence
1.3. Type II reaction assessed through clinical examination and patient reporting with type 2 reaction from the development of the reaction to its subsidence
2. Safety outcomes:
2.1. Severe side effects, defined as side effects that force the patient to stop treatment, monitored and recorded throughout the treatment period (baseline to 1 year)
2.2. Mild to moderate side effects monitored and recorded throughout the treatment period (baseline to 1 year)
3. Qualitative outcomes:
3.1. Impact of leprosy treatment on life assessed using patient interviews and quality of life questionnaires at 1 year
3.2. Perspective towards leprosy treatment assessed using patient interviews and attitude questionnaires at 1 year

Completion date
14/07/2025

Eligibility

Key inclusion criteria
1. Age 15 years and above
2. Multibacillary (MB) leprosy, defined as 5 or more skin lesions or extensive infiltration and/or diffuse skin involvement, classified as borderline tuberculoid, borderline lepromatous or polar lepromatous, as determined using the Ridley and Jopling classification system
3. Never treated before for leprosy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit

70 years

Sex
All

Key exclusion criteria
1. History of intolerance to one of the medications
2. Patients who are not able to come to the clinic every month during their treatment and during follow-up
3. Patients who do not give informed consent or are not capable of giving informed consent due to mental impairment
4. Immunocompromised patients diagnosed with HIV/AIDS and tuberculosis

Date of first enrolment
02/07/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
India

Study participating centre
The Leprosy Mission Home and Hospital
Belguma
Puruliya
India
723101

Study participating centre
The Leprosy Mission Hospital
Leprosy Clinic
Barabanki
India
225001

Study participating centre
The Leprosy Mission Hospital
Chandkhuri
Chandkhuri
India
495222

Study participating centre
TLM Community Hospital
Nandnagari
Delhi
India
110093

Sponsor information

Organisation
The Leprosy Mission Trust India

Funder(s)

Funder type
Government

Funder Name
Indian Council of Medical Research

Alternative Name(s)
Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, ..., ICMR, ICMRDELHI, ...

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

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?
Other files	Standard operating procedure documents		12/08/2024	No	No
Other files		25/08/2023	19/08/2024	No	No
Participant information sheet			01/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes