Clinical Trial Details (PDF Generation Date :- Tue, 25 Feb 2020 07:51:20 GMT)

CTRI Number	CTRI/2019/01/017310 [Registered on: 31/01/2019] - **Trial Registered Prospectively**
Last Modified On	22/01/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Other
Public Title of Study	Study on Tuberculosis resistant to treatment
Scientific Title of Study	Evaluation of the Efficacy and Safety of a Combination regimen of Bedaquiline, Delamanid, Linezolid and Clofazimine in Adults with Pre-extensive (Pre-XDR) and Extensively Drug-resistant Pulmonary Tuberculosis (XDR-TB):Prospective Cohort Study

Secondary IDs if Any

Secondary ID	Identifier
Version Number: 3.1, Version 3.1, Dated: 23-August -2018	Other

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	C Padmapriyadarsini
Designation	Scientist E
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> U.S. Agency for International Development Ronald Reagan Building 1300 Pennsylvania Ave Washington, D.C. 20523-0016 United States of America

Primary Sponsor

Primary Sponsor Details	
Name	ICMR National Institute for Research inTuberculosis
Address	No.1, Mayor Sathyamoorthy Road, Chetput, Chennai 600 031
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
India TB Research Consortium	Indian Council of Medical Research, V.Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rajesh solanki	BJ Medical College	Department of Pulmonary Medicine, Asarwa, Gujarat 380016 Ahmadabad GUJARAT	9825319344 rns04sec@yahoo.co.in
Dr Kiran Keny and Dr Lalit Anande	Group of Tuberculosis Hospitals	MDR-TB ward, Jerbai Wadia Rd, Sewree East, Mumbai, Maharashtra 400015 Mumbai MAHARASHTRA	08082130181 msgtb2012@gmail.com
C Padmapriyadarsini and R Sridhar	National Institute for Research in Tuberculosis and Govt. Hosptial of Thoracic Medicine	Department of Clinical Research, No.1 Mayor Sathyamoorthy Road, Chetput, Chennai 600031 77, Chennai Theni Hwy, Tambaram Sanatoruim, Chennai, 600047 Chennai TAMIL NADU	044-28369500 darsni69@hotmail.com
Dr Vikram Vohra	National Institute for Tuberculosis and Respiratory Diseases	Department of Pulmonary Medicine, Sri Aurobindo Marg New Delhi 110030 New Delhi DELHI	09810056922 drwvohra@gmail.com
Dr Anuj K Bhatnagar	Rajan Babu Institute of Pulmonary Medicine &	Department of Chest and Tuberculosis, GTB	9818321353

	Tuberculosis	Nagar, Kingsway Camp Delhi 1100009 North DELHI	anuuj1968@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
BJ Medical college, Ahamedabad	Approved	12/02/2019	No
Group of TB Hospitals, Mumbai	Approved	06/05/2019	No
National Institute for Research inTuberculosis AND Govt.Hopsital of Thoracic Medicine	Approved	29/11/2018	No
National Institute for Tuberculosis and Respiratory Diseases	Approved	26/12/2018	No
Rajan Babu Institute of Pulmonary Medicine and Tuberculosis	Approved	28/11/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	05/10/2018

Health Condition / Problems Studied

Health Type	Condition
Patients	Tuberculosis of lung

Intervention / Comparator Agent

Type	Name	Details
Intervention	Bedaquiline, Delmanaid, Linezolid, Clofazimine	24 -36 weeks (6-9 months): Bedaquiline (400mg) daily orally for 2 weeks followed by 200 mg thrice weekly for 22 weeks, Delamanid (100mg) twice daily oral for 24 weeks, Linezolid (600mg) daily orally for 24 weeks and Clofazimine (200mg) daily for 24 weeks to be taken orally
Comparator Agent	Not applicable	Not applicable

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1.Men or women aged 18 years and above 2.Multiple Drug Resistant TB documented by culture positive sputum for Mycobacterium tuberculosis with documented resistance to Rifampicin, with or without Isoniazid, AND Fluoroquinolone or a second line injectable (Pre-XDR) OR both Fluoroquinolone and a second line injectable (XDR) 3.A minimum of two positive sputum smears for acid-fast bacilli or at least one culture positive with negative sputum smears from specimens collected no more than 6-weeks 4.Chest X-Ray results consistent with pulmonary TB along with points 2 & 3 5.Body weight of ?30 kg 6.Willingness and ability to attend scheduled follow-up visits and undergo study assessments

	7.Provide written informed consent 8.Provide consent to HIV testing (9.If male or female participant of childbearing potential, willingness to use effective methods of birth control

Exclusion Criteria

Exclusion Criteria	
Details	1.Unstable disease i.e uncontrolled diabetes,cardiomyopathy,extra pulmonary TB,significant cardiac arrhythmias. 2.Current Hepatitis B & C, HIV, alcohol, barbiturates,amphetamine,narcotic use. 3.History of previous treatment with Bedaquiline or Delamanid. 4.Females with positive pregnancy test at screening or planning to conceive during study or within 6 months of cessation of drugs.Males planning to conceive during study or within 6 months of cessation of drugs. 5.Study participants with abnormal liver function test,hemogram,creatinine laboratory values. 6. Grade II peripheral newuropathy

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Cure rate at end of treatment with study regimen	6-9 months

Secondary Outcome

Outcome	Timepoints
1.Incidence of bacteriological relapse during 48 weeks post treatment follow-up. 2.Incidence of bacteriological failure or clinical failure during treatment period. 3.Treatment Emergent Adverse events of any type at any time while on combination treatment regimen,Discontinuation of study drugs for any reason,Death. 4.Time to sputum culture conversion from positive to negative in the liquid/LJ culture system.	6-9 months

Target Sample Size	**Total Sample Size=**165 **Sample Size from India=**165 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	01/02/2019
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**3 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NONE YET
Brief Summary	Currently treatment for drug resistant pulmonary TB is long-drawan (18-20

months) with an injectable and many toxic drugs. Inspite of this the cure rate is low and the default rates are high either dur to the long drawn treatment course or due to drug toxicity. With the availability of two new drugs, bedaquiline and delmanid with a new mechanism of action, there is an opportunity now to combine these drugs and plan a shorter and less toxic regimen for the management of these patients. Hence we propose to evaluate the efficacy of a new fully oral non-injectable treatment regimen of 6-9 months duration consisting of Bedaquiline (BDQ), Delamanid (DLM), Linezolid (LZD) and Clofazimine (CFZ) in adult patients with pre-extensive (pre-XDR) or extensively drug resistant (XDR) pulmonary tuberculosis. The study will also evaluate the safety and tolerability of this treatment regimen and also determine the time to sputum culture conversion with this combination treatment regimen. We will also determine the steady state blood levels of the new study drugs and their metabolites. This is a multi-centric study being planned in 5 sites of the country ver a period of 3 years.