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| A Comparative Multicentric Non-Inferiority Clinical Trial of WHOMBMDT with a New Monthly Chemotherapy Regime containing Rifampicin, Moxifloxacin and Clarithromycin (RMC) on Multibacillary patients from IndiaStandard Operating Procedure 9Follow up Assessment | | | |
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| **Table of Contents** | **Page** |
| 1. Purpose | 3 |
| 2. Policy Statement | 3 |
| 3. Background | 3 |
| 4. Scope | 3 |
| 5. Responsibilities | 3 |
| 6. Procedure | 4 |
| 7. References | 5 |

**1. PURPOSE**

To define RMC procedures for collecting, processing and recording follow-up assessments on the electronic form (Easy Research).

### **2. Background**

Current WHOMDT does not kill 100% bacteria even after a full course of treatment in a subset of patients harboring a large bacterial load thus continuing transmission of the disease responsible for endemicity in some countries. The duration of MDT is long and promotes noncompliance. MDT continues to be controversial with limited evidence support resulting in multiple reformulations since the last 40 years. This calls for a search for newer, more efficacious drugs with shorter duration of action evidenced with well-designed clinical trials. Relapse, advocated as the key outcome measure of efficacy of MDT, has its drawbacks. Relapse studies require long years of follow up. The gold standard test for viability was Mouse foot pad studies which is costly and time consuming. Hence, we propose Molecular Viability Assays as outcome measure of efficacy which are newer and better techniques to test viability faster. In this study, we propose to conduct a Randomized Controlled study comparing WHO MBMDT with a monthly regime consisting of currently most bactericidal and safe drugs of Rifampicin, Moxifloxacin and Clarithromycin in MB leprosy patients.

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| **Role** | **Responsibility** |
| RMC Principal  Investigator | * Ultimately responsible for ensuring clinical examination procedures are correctly implemented in the RMC study and that ICH GCP guidelines and this SOP are adhered to by all staff. |
| Local Study researchers | Responsible for:   * collecting all the information necessary from study participants. * Performing clinical evaluation. * Entry of all data into the electronic form (Easy Research). |
| Clinical Trial Co-ordinator | Responsible for:   * overseeing the collection of relevant data during follow-up assessments, ensuring accuracy and completeness. * ensuring that follow-up assessments are conducted in accordance with the trial protocol and regulatory requirements. |
| Pharmacist | * Responsible for dispensing study medication. |

### **6. PROCEDURE**

**6.1. Participant welcoming and general examination**

Each center will determine the optimal approach to ensure accurate assessment and the process for gathering all pertinent information. Nonetheless, it is mandatory that evaluation forms for all participants are completed while they are on-site at the center, with the local RMC researcher present alongside the participant.

* The local RMC researcher greets the participant and check the participant identification. Then, he/she will proceed with medical history, clinical assessment, physical examination, nerve examination and severity scale.
* During the assessment, the local RMC researcher will record the information on the electronic form.
* The local RMC researcher/ Clinician will review any sign or symptoms of adverse effects, and if necessary, an adverse effects form should be fill up and manage accordingly (refer to SOP 10).

**6.2. Participant discharge**

* The local RMC researcher will register on the participant card the next appointment date.
* The local RMC researcher will review medication and what to expect during the study and she/he will give all the warnings regarding adverse events including how to proceed if any problem. Then the participant will be forwarded to the pharmacist.
* The pharmacist will check participant’s identification and then give the participant a package containing the study medication with the exact doses until the next appointment. The pharmacist will explain the medication.
* The pharmacist will reinforce instructions and verify the date of the next appointment.
* The pharmacist or the local RMC researcher will check the completion of this procedure on the electronic form.
  1. **Late Clinic Attendances**
* If a trial subject does not attend a scheduled assessment, then they will be contacted and asked to come as soon as possible for their assessment. It is essential that the date of the attendance is recorded. The number of the assessment should not be changed regardless of how late the assessment is carried out.
* The next assessment after this should be scheduled as per the original assessment. In the event of missed study investigations by a participant, they should undergo these assessments during their next scheduled visit.
* A default or withold for 27 days will be allowed in the followup . More than 27 days of default will result in withdrawing from the trial.

**6.5 Unscheduled Clinic Attendances/ examinations**

* All unscheduled examinations or attendances should be recorded as unscheduled visit on electronic data collection form.
* It should be documented if the clinician feels the attendance is related to RMC

6.6 Incentives :

* + An amount of 500INR will be disbursed to every patient on the trial as a contribution towards the travel costs.

**7. REFERENCES**

RMC Protocol