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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 13Return/Disposal of RMC trial Drugs | | | |
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**1.** **PURPOSE**

This document describes the process of return and disposal of RMC trial drug.

### 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.

**3. Scope**

This document applies to all procedures related to the return and disposal of RMC drug.

**4. Responsibilities**

|  |  |
| --- | --- |
| **Role** | **Responsibility** |
| RMC Principal  Investigator | Responsible for:   * ensuring compliance with RMC study procedures and oversee drug disposal process. * ensuring that all study staff involved in drug handling and disposal are adequately trained in proper procedures. |
| Local Study researcher | * Maintain accurate and detailed records of the trial drugs, including receipt, storage, dispensing, and return or destruction of drugs. |
| Clinical Trial Co-ordinator | * Act as a liaison between the PI, study sponsor, and regulatory authorities regarding drug disposal activities. * Ensure that all records related to drug disposal are securely maintained and easily accessible. * Address any issues or discrepancies related to drug disposal promptly. |
| Pharmacist (at site) | * ensuring appropriate records of destruction are maintained. * arranging and/or carrying out destruction according to the agreed procedure. |

### 5. PROCEDURE

1. When it no longer becomes necessary for the Center to keep an inventory of the RMC trial drug, it shall be returned to the sponsor or destroyed. Examples of such times would include:

* The Study is completed or discontinued.
* The Investigational Product has expired.
* The Investigational Product is damaged, returned by a subject or otherwise unfit for use.

2. Returning the Investigational Product to the sponsor shall be the preferred method of clearing out the inventory as opposed to alternative methods of disposal.

3. In the event the Sponsor desires that the RMC trial drug be disposed of by the Center as opposed to being returned, it shall be done according to the Sponsor’s request provided it comply with all applicable country, state, local laws and other relevant Center policies.

4. All RMC trial drugs used and unused must be accounted for by the local study researcher and the pharmacist at site. Disposal of used or unused investigational products must be initiated only after the written instruction from the Sponsor/Clinical trial co-ordinator had been obtained.

5. Once accounted for, if the sponsor does not request that drugs need to be returned, then the products may be disposed of. The procedure for destroying used study drugs is as follows:

* All RMC trial drugs are disposed and destroyed in accordance to the TLMTI waste disposal protocol.
* The accounted drugs are prepared and placed in a biohazard bag, secured and taped closed.
* The bag with RMC trial drug is kept locked at site until it may be released to biomedical waste management personnel.
* Proper documentation that the drugs were disposed of according to policy is done (Refer appendix)

**Appendix 1**

**Destruction/Disposal of RMC clinical trial drugs**

|  |
| --- |
| **Study Name/Protocol:** |
| **PI:** |
| **Clinical Trial Co-ordinator:** |
| **Site:** |
| **Pharmacist:** |
| **Sponsor:** |

***Authorisation checks***

|  |  |
| --- | --- |
| Description of RMC trial drug for destruction  *Note: if multiple drugs per study, then complete one form for each* |  |
| Reason for destruction: |  |
| Decision agreed by/at meeting (date): |  |
| Date of last monitoring visit: |  |
| Any outstanding RMC trial drug related issues: |  |
| Clinical Study Report complete: | Yes No |
| Accountability logs verified and up to date | Yes No |
| How will RMC trial drug be destroyed and by who? |  |

**Description of RMC trial drug for destruction/disposal**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of RMC trial drug** | **Tick** | **Details or attach a detailed report** | **Quantity destroyed** |
| Patient returns |  | **Participant numbers** |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **Unused stock** |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |
| **Expired stock** |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |
| **Damaged stock** |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |
|  |  | **BN: Exp:** |  |

Destruction/disposal authorized by: ……………………………………………………………………….

I authorise the destruction/disposal of all above-described RMC trial drugs for this study

|  |  |
| --- | --- |
| Name: |  |
| Role: |  |
| Date: |  |

**Pharmacy to complete**

All RMC trial drugs described above has been verified by clinical trial co-ordinator and there are no outstanding issues relating to the RMC trial drugs for these subjects/ this trial. The above documented returns have been placed for destruction in the relevant waste container and sealed as per the TLMTI policy for the disposal of pharmaceutical waste.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Destroyed by: |  | Signature: |  | Date: |  |
| Witnessed by: |  | Signature: |  | Date: |  |

File original in Pharmacy Site File, a copy should be sent to the trial co-ordinator for evidence of action.