Patient Information Sheet

Study Title: RMC clinical trial in MB leprosy

Introduction:

We invite you to take part in a research study to evaluate a new treatment for leprosy. Leprosy is a disease caused by bacteria, and current treatments do not always work perfectly. This research aims to find a better treatment with fewer side effects.

Objective:

We will compare a new treatment called "RMC" to the standard treatment recommended by the World Health Organization (WHO). RMC includes three medicines: Rifampicin, Moxifloxacin, and Clarithromycin, given once a month. Both treatments last for 12 months.

Who Can Participate?

You can participate if you are newly diagnosed with leprosy and haven't had any treatment before. We need your written consent to include you in the study.

What We Will Do:

1. You will be randomly assigned to one of the two treatment groups.

2. We will collect samples from you at specific times to check for the leprosy bacteria using modern techniques.

3. We will examine your skin lesions and evaluate your clinical improvement.

4. We will monitor any nerve pain or reactions.

5. We will assess the impact of the treatment on your life and how you feel about it.

Expected Outcomes:

We aim to achieve the following outcomes:

Primary Efficacy Outcomes:

1. Molecular Outcomes: We want to reduce the number of bacteria in your body using advanced techniques.

2. Clinical Outcomes: We expect your skin lesions to fully heal or show improvement.

3. Pathological Outcomes: The level of bacteria in your body should decrease.

Secondary Efficacy Outcomes:

1. Immunological Outcomes: We will monitor any nerve pain or reactions.

2. Safety Outcomes: We will keep an eye on side effects and their severity.

3. Qualitative Outcomes: We'll ask how the treatment affects your life and how you feel about it.

Benefits:

- You may receive a more effective treatment for leprosy.

- Your participation will contribute to improving leprosy treatment for others.

Risks:

- There may be side effects from the medicines, but we will monitor and manage them.

Participation is Voluntary:

Your participation is completely voluntary. If you decide to participate, you can change your mind at any time without any consequences.

Confidentiality:

All your information will be kept confidential, and your identity will not be disclosed.

Contact Information:

If you have any questions or concerns,

please contact

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