

Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

MaPs in ENL

Session 1- Introduction, design and structure

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Training Session 1

Introduction to MaPs

Study design

Structure

MaPs in ENL



Methotrexate (MTX) and Prednisolone Study in Erythema Nodosum Leprosum is a multicentre double blind randomised clinical trial

- Bangladesh, Ethiopia, India (2 sites), Indonesia, and Nepal.
- Investigate the efficacy of <u>WEEKLY</u> oral MTX for ENL in leprosy
- WEEKLY MTX used in conjunction with prednisolone for ENL will improve the clinical outcomes for patients with ENL
- Quality of Life

Study Design

- Multicentre double blind randomised clinical trial controlled with placebo with 2 treatment arms
- Double blind
 - Participants and researchers won't know which treatment
 - Pharmacist will hold the key
- Randomisation
 - Participants will be allocated by chance in each treatment
 - To control bias
- Controlled by placebo
 - Active medication and placebo
 - Both groups will receive standard of care

MaPs in ENL

Recruitment

Informed consent

Laboratory test screening

Eligibility assessment

Randomisation

Intervention group
WEEKLY MTX +
Prednisolone
48 weeks WEEKLY MTX
20 weeks Prednisolone

Control Group
Placebo + Prednisolone
48 weeks dummy tablets
20 weeks Prednisolone

Follow-up for 60 weeks

Analysis

Participants will be randomly allocated to one of the two study arms using randomisation tables

Summary

- MaPs in ENL in a double-blind randomised clinical trial in 6 leprosy services
- Objective: to investigate the efficacy of <u>WEEKLY</u> oral MTX for ENL
- Participants will be randomised into 2 arms (MTX + prednisolone versus placebo + prednisolone)
- Follow up 60 weeks