



# Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

## MaPs in ENL

### Training session 5 – Recruitment process

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# ENLIST



# Recruitment

- **Recruitment process**
  - Identify possible participants
  
- **Inclusion Criteria and Exclusion Criteria**

Identifying possible participants

**Individuals with leprosy complicated by ENL**

**18 -60 years old**

**Clinical examination**

**10 or more tender papular or nodular ENL skin lesions**

**ENLIST ENL Severity Scale ( EESS) 9 or more**

**With deteriorating symptoms**

# Inclusion criteria – Acute ENL

- On no current anti- ENL treatment OR
- On up to 30mg per day or equivalent alternative corticosteroid dose OR
- On thalidomide or other anti-ENL medication OR
- On a combination of prednisolone (up to 30mg) and another anti-ENL medication (thalidomide, clofazimine, azathioprine, pentoxifylline, ciclosporin, minocycline)

Acute ENL is defined as occurring if a patient has either a first episode of ENL less than 24 weeks duration or experiences a second or subsequent episode of ENL which lasts less than 24 weeks and occurs 84 days (ie 12 weeks) or more after stopping treatment for ENL

# Inclusion criteria – Recurrent/Chronic ENL

- On no current anti- ENL treatment

or

- On prednisolone 10-30mg per day (inclusive) or equivalent alternative corticosteroid dose

or

- On thalidomide or other anti-ENL medication

or

- On a combination of prednisolone (up to 30mg) and another anti-ENL medication (thalidomide, clofazimine, azathioprine, pentoxifylline, ciclosporin, minocycline)

**Recurrent ENL** is defined as occurring if a patient experienced a second or subsequent episode of ENL occurring between 28 and 84 days of stopping treatment for ENL .

**Chronic ENL** is defined as occurring for more than 24 weeks during which a patient has required ENL treatment either continuously or where any treatment free period had been 27 days or less.

# Exclusion Criteria

- Individuals who were first diagnosed with ENL more than 4 years prior to enrolment
- Individuals less than 18 years old or older than 60 years
- **Individuals weighing less than 35kg**
- **Individuals with 9 or fewer tender, popular or nodular ENL skin lesions**
- **Individuals with an EESS score of 8 or less**
- Women of child bearing capacity who decline to use two forms of adequate contraception
- and men who intent to impregnate his partner during the period of the study.
- Pregnant or breastfeeding women
- Individuals with recurrent or chronic ENL who deteriorate on a dose of prednisolone less than 10 mg or more than 30 mg
- Individuals who have taken methotrexate by any route for the last 12 weeks
- Individuals with a hypersensitivity to methotrexate or a recognised contraindication (please see Methotrexate information sheet)
- Individuals currently diagnosed with Type 1 reaction or Lucio's phenomenon
- **Individuals with the following abnormalities in screening investigations**
  - **Haemoglobin < 10 g/dL**
  - **White blood cells < 3.0 x 10<sup>9</sup>/l**
  - **Neutrophils < 1.5 x 10<sup>9</sup>/l**
  - **Platelets < 100 x 10<sup>9</sup>/l**
  - **AST and ALT > 2 times the upper limit of normal range**
  - **Bilirubin > 5mg/dl (85,5 µmol/l)**
  - **Hypoalbuminemia <3.5 g/dl**
- Positive serology for HIV, Hepatitis B or C
- Evidence of tuberculosis or pulmonary fibrosis
- A history of chronic liver disease or excessive alcohol or illicit substance consumption
- Individuals with severe inter-current infections, uncontrolled diabetes, active peptic ulcer disease, untreated malignancy
- Individuals unable to attend regularly for assessment or monitoring

# Summary

- **Patients with leprosy complicated by Acute or Recurrent/Chronic ENL**
  - Definition of Acute, Recurrent and Chronic
- **Inclusion and exclusion criteria**
  - REDCap will help with inclusion and exclusion criteria
  - Some exclusion criteria can change