



Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

MaPs in ENL

Training session 7 – Laboratory tests and chest X-ray

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Tests

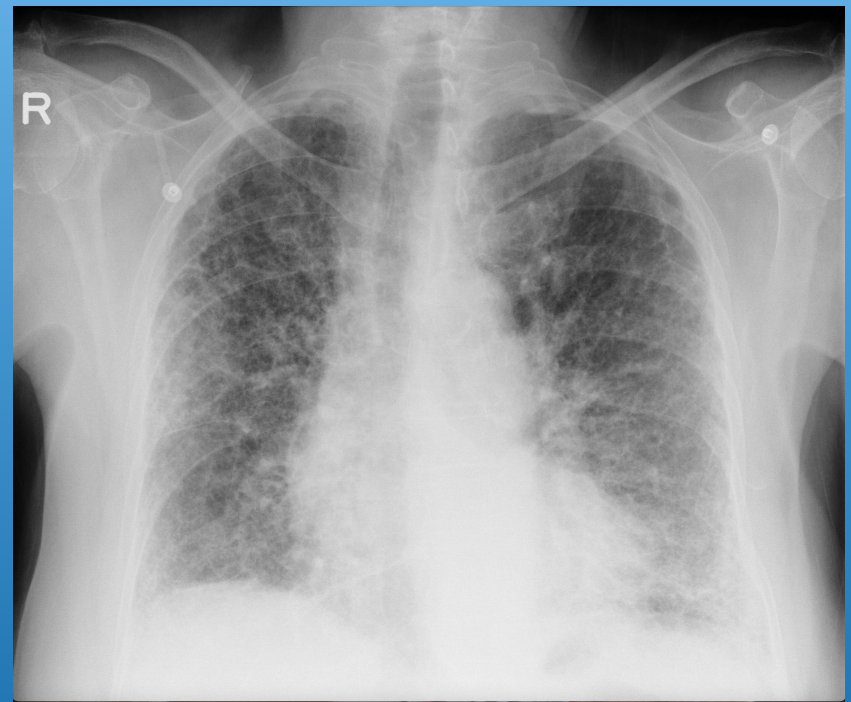
- **Laboratory tests for recruitment**
- **Chest X-ray**
- **Laboratory tests follow up**
- **Results – REDCap**
- **Monitoring adverse events**
- **Monitoring treatment**

Recruitment tests

- Full blood count
- Blood glucose
- Renal function including potassium and creatinine
- Liver function tests: bilirubin and transaminases
- Urine pregnancy test for women of child bearing potential
- **Hepatitis B serology**
- **Hepatitis C serology**
- **HIV antibody test**

Chest X-Ray

**CHEST XRAY SHOULD BE
OBTAINED TO RULE OUT TB
AND FIBROSIS**



Follow up laboratory tests

- **Full blood count**
- **Blood glucose**
- **Renal function including potassium and creatinine**
- **Liver function tests: bilirubin and transaminases**
- **Urine pregnancy test for women of child bearing potential**

Week	Assessment	Investigations
0	Recruitment	FBC/Renal + Liver functions/ glucose/ urine pregnancy/ HIV, Hepatitis B and C Chest x-ray
1	1 st visit	FBC/Renal/LFT
2	Follow up	FBC/Renal/LFT
4	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
8	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
10	Follow up	FBC/Renal/LFT
12	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
16	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
20	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
24	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
28	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
32	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
36	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
40	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
44	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
48	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
52	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
56	Follow up	FBC/Renal/LFT/ Glucose Urine pregnancy test
60	Lasty visit	FBC/Renal/LFT/ Glucose Urine pregnancy test

Results

- Check last laboratory results
- Enter on REDCap the latest results
- REDCap will flag results abnormalities
- Report when results abnormalities → Actions and follow up

Abnormality	Action	Follow up
Total white blood cell (WBC) count < 3.0 x 10⁹ cells/l	HOLD study medication	Repeat tests if continue low WBC count < 3.0 x 10 ⁹ cells/l then withdraw participant
Neutrophils < 1.0 x 10⁹ cells/l*	HOLD study medication	
Platelets <100,000/mm³	HOLD study medication	Repeat tests if continue platelets are < 100,000/mm ³ then withdraw participant
MCV > 105fl*	Consider holding dose of study medication -> check serum B12, folate and thyroid functions tests	
AST and ALT increased by less than two times the upper limit of normal (ULN)	Continue study medication Repeat tests in 2-4 weeks	If LFTs are less than twice ULN resume MTX and monitor again in 4 weeks
AST and ALT greater than 2 but less than or equal to 3 times the normal limit	HOLD the study medication Repeat LFTs in 4 weeks Consider other risk factors (including alcohol consumption)	If LFTs are less than twice ULN resume MTX and monitor again in 4 weeks
AST and ALT greater 3 times the normal	Withdrawal from study	Monitor until normal or cause identified
Creatinine > 2 x ULN	HOLD study medication and repeat in 4 weeks	If repeat creatinine > 2 x ULN withdraw participant
Positive urine pregnancy test	Withdrawal from study	Follow up pre-natal and delivery

Monitoring treatment

- Full blood count
- Blood glucose
- Renal function including potassium and creatinine
- Liver function tests: bilirubin and transaminases

Summary

- **Recruitment tests and chest – x ray**
- **Follow up tests**
- **Monitoring Adverse events and treatment**
- **Actions**