



Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

MaPs in ENL

Training session 8 – Allocation concealment - randomisation

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Blinding process and randomisation

- **Blind study**
 - Why?
 - Code
 - Breaking the code
- **Randomisation process**

Allocation Concealment



- **MaPs is a double-blind clinical trial**
- **Blinding is important for study validity**
- **Knowledge of group allocations may affect behaviour in the trial**
- **Unblinding**



Randomisation

- Random allocation is done to the participants
- MaPs – 2 arms (methotrexate and placebo)
- Guarantee both groups are comparable
- Reduce the systematic bias



Summary

- **MaPs is a double - blind clinical trial**
- **Allocation concealment -blinding process is a gold standard**
 - **When will break the code**
- **Randomisation**
- **Validity and study power**