

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



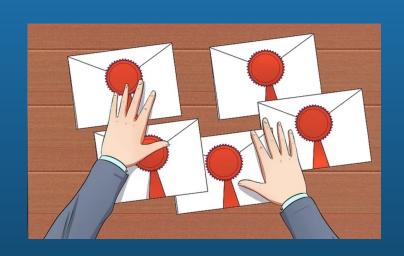
- MaPs is a double-blind clinical trial
- Blinding is important for study validity
- Knowledge of group allocations may affect behaviour in the trial
- Unblinding



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