Double-blind, placebo controlled trial.

Patients with CD who entered remission after 16 to 24w of treatment with 25mg of MTX IM once weekly were randomised to:

MTX 15 mg IM every week or placebo for 40 weeks. No other treatments were permitted.

<u>Primary endpoints:</u> Ocurrence of relapse of CD defined as CDAI of at least 100 points above baseline.

## **Results:**

- At w40, 65% MTX vs 39% placebo were in remission, p=0.04
- Steroid need during follow-up 28% MTX vs 58% placebo, p=0.01
- No severe adverse reported in either group.

## **Conclusion:**

In patients with Crohn's disease who enter remission after treatment with methotrexate, a low dose of methotrexate maintains remission.

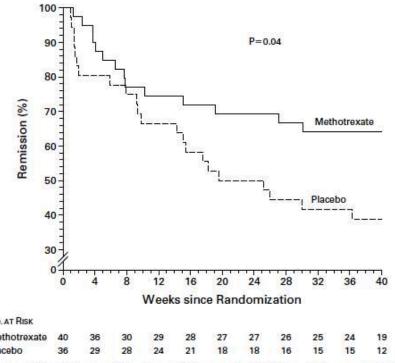


Figure 1. Kaplan-Meier Estimates of the Time to Relapse in the Methotrexate Group and the Placebo Group.

