

50w double-blind placebo controlled trial.
Moderate-severe CD patients were randomised to:
Infliximab (weeks 1,3,7,14 and q8w)+ methotrexate (initial dose 10 mg/w escalated to 25 mg per week) vs infliximab alone.
Patients on prednisone for 6w, needing to taper the dose every week.

Primary outcome: time to treatment failure defined as lack of steroid free remission in w14 or failure to maintain remission in w50

Results:

- Treatment failure w50: was 30.6% in IFX+MTX vs 29.8% IFX, p=0.63
- Prespecified subgroup analyses failed to show a benefit in patients with short disease duration or high CRP
- Patients on IFX+MTX less likely to develop immunogenicity, p=0.01

Conclusions:

The combination of infliximab and methotrexate, although safe, was no more effective than infliximab alone in patients with CD receiving treatment with prednisone.

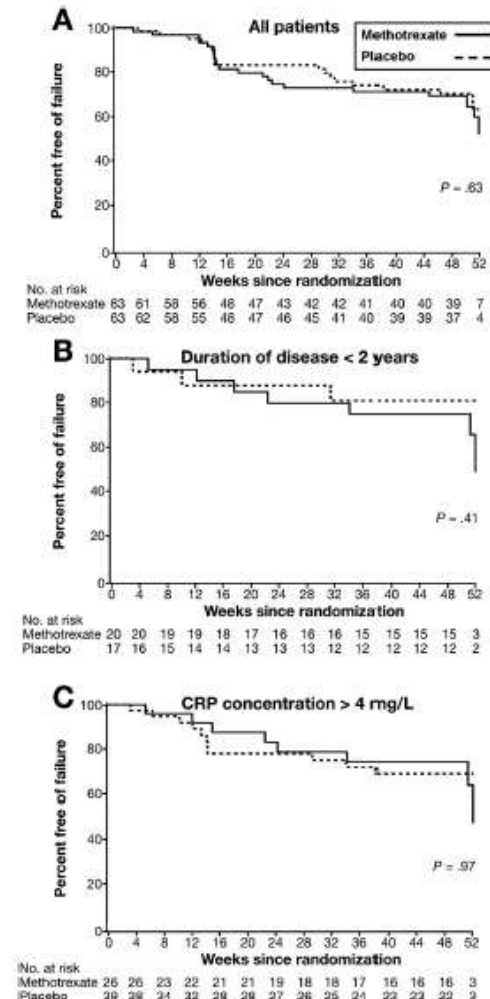


Figure 1. Kaplan-Meier estimates of the time to treatment failure. (A) All patients. (B) Duration of disease shorter than 2 years. (C) CRP concentration greater than 4 mg/L.

