

Multicenter, randomized double-blind, placebo-controlled pragmatic trial.

Patients with pediatric Crohn's disease initiating IFX or ADA were randomized to methotrexate combination or placebo for 12-36 months.

Primary endpoints: Time to treatment failure.

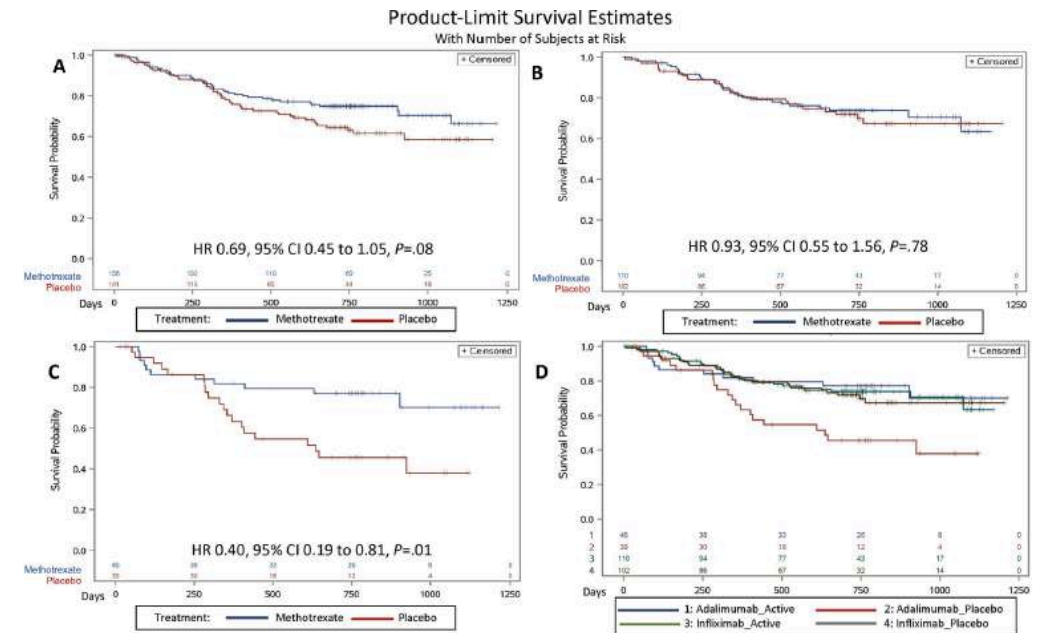
Results: N=297

- Time to treatment failure did not differ by study arm (HR 0.69, 95%CI 0.45-1.05).
- Among IFX initiators there were no differences in mono vs combotherapy.
- Among ADA initiators combotherapy was associated with longer time to treatment failure (HR 0.40, 95%CI 0.19-0.81).
- There was a trend toward lower anti drug antibody formation in combotherapy arm but was not significant for both drugs.

### Conclusion:

In pediatric CD patients, those on adalimumab but not infliximab initiators with combination therapy with methotrexate had a 2-fold reduction in treatment failure.

## Comparative Effectiveness of Anti-TNF in combination with Low Dose Methotrexate vs Anti-TNF Monotherapy in Pediatric Crohn's Disease: A pragmatic Randomized Trial



**Figure 2.** (A) Kaplan-Meier analysis of the time-to-event in the overall population. (B) Kaplan-Meier analysis among infliximab initiators. (C) Kaplan-Meier analysis among adalimumab initiators. (D) Kaplan-Meier curves broken out by both anti-TNF agent and combination vs monotherapy.

