

Multicenter, double-blind, randomized, placebo-controlled trial
 Patients with CD and one or more draining abdominal or perianal fistulas of at least three months' duration received 5mg/kg IFX (0,2,6 and q8w thereafter) those who responded at w10 and w14 were randomly assigned to 5mg/kg q8w or placebo.
 *Setons permitted but required to be removed by week 2.

Primary endpoints: Time to loss of response

Results:

- Time to loss of response longer IFX 40 weeks vs 14w placebo, $p < 0.001$
- At w54 complete absence of draining fistulas 36% IFX vs 19% placebo, $p = 0.009$
- At w54 maintained response was observed in 46% IFX vs 23% placebo, $p = 0.001$

Conclusion:

Patients with fistulizing Crohn's disease who have a response to induction therapy with infliximab have an increased likelihood of a sustained response over a 54-week period if infliximab treatment is continued every 8 weeks.

