

Randomized double blind trial. 2 arms:

IFX 5mg/kg (0,2,6 and q8w thereafter) vs AZA 2.5mg/kg vs IFX+AZA

Primary end point: corticosteroid-free clinical remission at w26;

Secondary end points: mucosal healing w26, rate of any remission, response-70, response-100, IBDQ score, steroid dose, CRP level from baseline to w26.

Results:

- Steroid free remission w26: 56.8% combo vs 44.4% IFX alone vs 30% AZA; $p=0.006$ / $p<0.001$
- Mucosal healing w26: combo 43.9% vs 30.1% IFX alone vs 16.5% AZA; $p=0.02$ / $p<0.001$
- Antibodies w30: 0.9% combo vs 14.6% IFX; $p<0.001$
- No differences in serious infections.

Conclusions:

Patients with moderate to severe active CD treated with IFX+ AZA or IFX monotherapy were more likely to have steroid free remission than AZA alone.

Combotherapy superior to both monotherapies.

Infliximab, Azathioprine, or Combination Therapy for CD

