

Randomized, double-blind trial in patients with CD naïve to biologics, All patients induction with IFX+ immunosuppressant. At w14 randomisation to:

Control group: dose increased by 5 or 10 mg/kg if CDAI >220
DIS 1 → IFX increased by 2.5mg/kg (max 2 times)**; DIS 2 → IFX increase by 5mg/kg (1 time)**

Primary outcome:

Corticosteroid-free remission (CDAI <150) at all visits between w22 and w54 associated with the absence of ulcers at w54 and no surgery for bowel resection or abscess and no new fistula.

Results:

- The primary endpoint was reached by 33% DIS1 group, 27% DIS2 group, and 40% in the control group (p 0.50).

Conclusions:

Increasing dose of IFX based on a combination of symptoms, biomarkers, and serum drug concentrations does not lead to corticosteroid-free clinical remission in a larger proportion of patients than increasing dose based on symptoms alone.

**Dose escalation in group DIS1 and DIS2 when 1 of the following criteria were met, in hierarchical order: (1) CDAI >220 with an elevated serum CRP (>5 mg/L) and/or fecal calprotectin (>250 mg/g); (2) CDAI 150 to 220 for 2 consecutive weeks with an elevated CRP and/or fecal calprotectin; (3) IFX serum concentration at trough (TL) <1 mg/mL at the previous measurement; (4) IFX TL 1–3 mg/mL at the previous measurement and 5) IFX TL 3 to 10 mg/mL with a drop by >50% compared with the week 14 IFX concentration.

Increasing Infliximab Dose Based on Symptoms, Biomarkers, and Serum Drug Concentrations Does Not Increase Clinical, Endoscopic, and Corticosteroid-Free Remission in Patients With Active Luminal CD

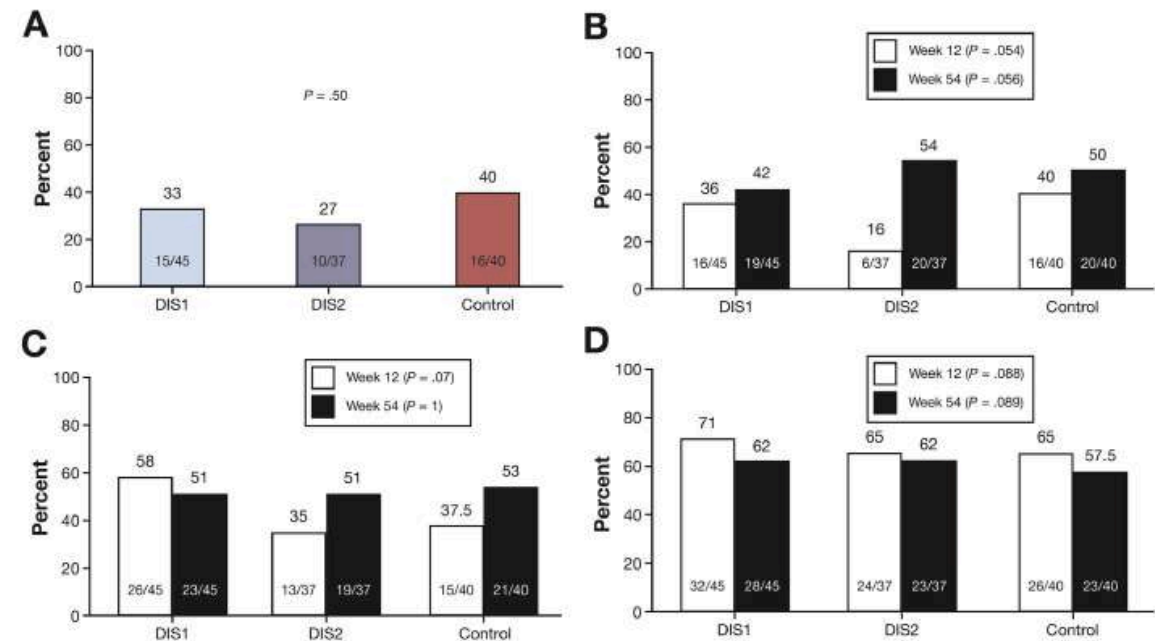


Figure 2. Primary endpoint and main secondary endpoints of the trial. (A) Proportion of patients in remission off glucocorticosteroids from week 22 to week 54, absence of ulcers at week 54, and no new fistula or surgery. (B) Proportion of patients with absence of ulcers at weeks 12 and 54. (C) Proportion of patients with CDEIS <3 at weeks 12 and 54. (D) Proportion of patients with decrease of CDEIS >50% from inclusion at weeks 12 and 54.