

1-year randomized controlled trial.

Patients with moderate-severe IBD were randomized to:

- IFX dosing based on their clinical features or continued dosing based on Trough concentrations (TC) (maintenance phase)

*IFX dose escalated or reduced using an algorithm to reach a target TC of 3–7 mg/mL in all patients (optimization phase).

Primary outcome: Primary end point was defined as the proportion of patients in each group in clinical HBI 4 for CD and partial Mayo score <2 and biological (CRP<5 mg/L) remission at year 1 after optimization

Results:

- Based on clinical features 66% and 69% whose dosing was based on TC achieved remission, the primary end point (p 0.686).
- Disease relapsed in 21 patients who received clinically based dosing (17%) and 9 patients who received concentration-based dosing (7%) (p 0.018).

Conclusion: Targeting patients' infliximab TCs to 3–7 mg/mL results in a more efficient use of the drug. After dose optimization, continued concentration-based dosing was not superior to clinically based dosing for achieving remission after 1 year, but was associated with fewer flares during the course of treatment.

Figure 3. Illustrates the effect of concentration-based dose escalation (A, C) and dose reduction (B, D) during the optimization phase on the proportion of patients in remission (A, B) and on the CRP concentration (mg/L) (C, D) for patients with CD and UC. Patients who discontinued the optimization phase due to personal reasons (ie, noncompliant with treatment algorithm or consent withdrawal) were excluded from the analysis (1 CD and 4 UC patients from the dose-escalation group and 1 UC patient from the dose-reduction group). Remission was defined as an HBI ≤ 4 or PMS ≤ 2 with no individual subscore of >1.

