

Conclusions: We identified clinical and genetic markers associated with infliximab response in patients with IBD. Our findings could provide insights to maximise the efficacy of infliximab therapy in IBD.

References

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DOP56
Dashboard driven vs. conventional dosing of infliximab in inflammatory bowel disease patients: the PRECISION trial

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Background: Loss of response to infliximab (IFX) complicates the management of inflammatory bowel disease (IBD). Up to date, no prospective study has demonstrated the benefit of proactive dose adjustment based on serum IFX levels. However, more personalised dosing strategies using a dashboard to achieve and maintain well-defined IFX target trough levels (TLs) may prevent loss of response. The aim of the PRECISION trial was to investigate the efficacy of dashboard-driven IFX dosing in IBD patients during 1 year.
Methods: In this multi-centre 1:1 randomised prospective trial, patients in clinical remission (Harvey–Bradshaw Index [HBI] ≤4 for Crohn’s disease [CD] or partial mayo score [PM] ≤2 for ulcerative colitis [UC]) receiving IFX maintenance treatment were included. Patients in the precision dosing group (PG) received IFX dosing guided by a Bayesian pharmacokinetic model, aiming to achieve and maintain an IFX TL of 3 µg/ml by treatment (de-)escalation as indicated by the dashboard.¹ Patients in the control group (CG) continued IFX treatment regimen given prior to randomisation without dose adaptation. Biochemical remission was defined as a faecal calprotectin <250 µg/g and CRP < 0.5 mg/l. Clinical loss of response was defined as an HBI >4 or PM score >2 at two consecutive visits.
Results: In total, 80 patients were included (66 CD and 14 UC). Baseline characteristics are listed in Table 1.

Characteristic	PG (N = 40)	CG (N = 40)
IFX treatment duration in years [IQR]	3.5 (2–7.8)	4.0 (1.3–5.8)
Serum CRP mg/l [IQR]	2.0 (0.9–5.3)	2.1 (1.0–6.5)
Serum TL µg/ml [IQR]	3.7 (1.6–6.4)	3.0 (1.9–5.2)
Serum albumin g/l [IQR]	43 (41–45)	42 (40–45)
Biochemical remission, n (%)	25 (62.5)	22 (55)
Standard IFX treatment regimen	25 (62.5)	23 (57.5)
Intensified IFX treatment regimen	11 (27.5)	13 (32.5)
De-intensified IFX treatment regimen	4 (10)	4 (10)
Combination therapy with IM	15 (37.5)	17 (42.5)

Baseline patient characteristics per treatment group. Values are median (interquartile range). IM, immunomodulator (thiopurine or methotrexate). Per protocol analysis showed loss of clinical response in 14/39 (36%) patients in the CG compared with 4/32 (13%) patients in the PG (*p* = 0.03). Three patients (7.5%) in the PG were considered failures because of re-opening of their perianal fistula after dose de-escalation to achieve a TL of 3 µg/ml. Time to relapse was evaluated using Kaplan–Meier analysis (Figure 1).

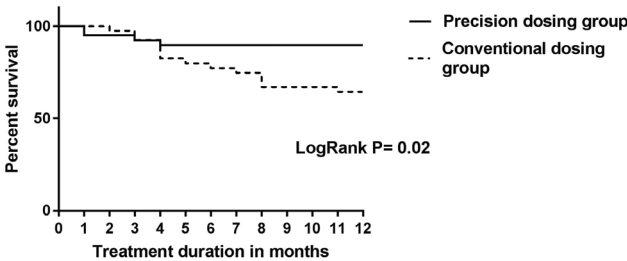


Figure 1. Kaplan–Meier
Conclusions: The PRECISION study is the first prospective trial demonstrating a clinical benefit from personalised dosing in IBD patients. Dashboard-guided dosing resulted in a significant higher proportion of patients who maintained clinical remission during 1 year of treatment compared with patients that continued treatment without proactive adjustments. In patients with perianal disease, de-escalating treatment to obtain an IFX TL of 3 µg/ml resulted in re-opening of their old fistula, suggesting that, in these patients, higher TLs are needed for disease control.
Reference
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DOP57
Monitoring response to anti-TNF therapy in ulcerative colitis patients by gastrointestinal ultrasound: sub-analysis from TRUST&UC

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Background: In ulcerative colitis GIUS (GastroIntestinal UltraSound) is discussed to be a reliable surrogate parameter for inflammatory activity next to faecal calprotectin (FC), and to some extend