2022. TISkids

RCT/ IFX /paediatric CD/Induction

First-line treatment with infliximab versus conventional treatment in children with newly diagnosed moderate-to- severe Crohn's disease: an open-label multicentre randomised controlled trial

Open-label, randomised controlled trial.
Moderate-severe paediatric CD new diagnosed.
Randomsied to: IFX 5mg/kg (0,2,6,14,22) vs conventional therapy (EEN or oral prednisolone (1mg/kg maximum 40 mg/d))

Primary endpoint: clinical remission on azathioprine as wPCDAI <12.5 at w52.
ITT analysis

Results:
- w10, 59% IFX vs 34% (conventional group) in clinical remission, p=0.021; and endoscopic remission 59% vs 17%, p=0.001.
- w52: no differences in clinical remission p=0.42. 41% on IFX were in remission on AZA alone without escalation therapy vs 15% in the conventional group, p=0.004.

Conclusions:
FL-IFX was superior to conventional treatment in achieving short-term clinical and endoscopic remission, and had greater likelihood of maintaining clinical remission at week 52 on azathioprine monotherapy.

Table 5 Findings at week 52 per treatment group

	First-line IFX	Conventional	P value
wPCDAI, median (IQR)	7.5 (0–15)	10 (0–17.5)	0.476
Clinical remission, n (%)	33/47 (70)	26/46 (57)	0.420
Clinical remission in patients on immunomodulator monotherapy, n (%)	22/29 (76)	12/18 (67)	0.958
Endoscopic remission, n (%)*	5/18 (28)	5/14 (36)	0.630
SES-CD, median (IQR)	7 (2–7)	6 (0–10)	0.961
Fcal <100 µg/g, n (%)	17/48 (35)	9/47 (19)	0.120

Clinical remission is defined as a wPCDAI <12.5. Endoscopic remission was defined as a SES-CD <3. The group of patients on immunomodulator monotherapy comprised patients on azathioprine (n=46) and methotrexate (n=1). Baseline characteristics of these patients are similar (online supplemental table 2C).
*Eighteen FL-IFX patients and 14 conventionally treated patients consented for endoscopy at week 52.
Fcal, faecal calprotectin; IFX, infliximab; SES-CD, Simple Endoscopic Score for Crohn's Disease; wPCDAI, weighted Paediatric Crohn's Disease Activity Index.

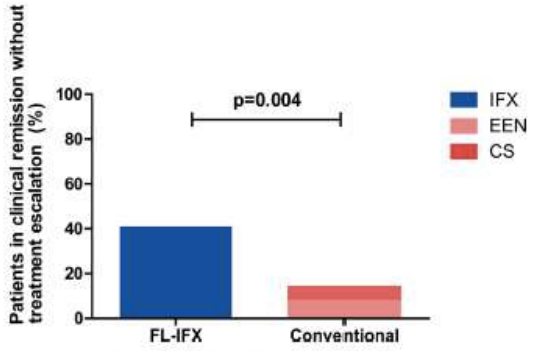

Figure 4 Proportion of patients in clinical remission without treatment escalation. The proportion of patients in clinical remission, defined as a weighted Paediatric Crohn's Disease Activity Index <12.5, without treatment escalation at 52 weeks after the start of induction therapy. CS, corticosteroid; EEN, exclusive enteral nutrition; FL-IFX, first-line infliximab.

Jongsma MME et al. Gut 2022;71:34–42.