

Open label, randomised double blind trial, single center. Proof-of-concept.

Patients with CD within a week following surgery were randomised to infliximab 5mg/kg (0,2,6 and q8w) or control arm.

Primary endpoints: Clinical remission at months 12 and 36.

#### Results:

- Cumulative remission at 12 months rates based on CDAI were 86.7% IFX vs 75% in control, p=ns
- Cumulative remission rates based on IOIBD score 100% IFX vs 68.8% control, p=0.0203
- Endoscopic remission at 12 months, 78.6% IFX vs 18.8% control. P=0.004
- At 36 months CDAI remission, 80% IFX vs 75% control, p=ns

#### Conclusion:

An early intervention with IFX monotherapy should prevent clinical, serological, and endoscopic CD recurrence following ileocolic resection. Thiopurine naivety and eliminating the initial loading dose of IFX might minimize serious AEs.

### Scheduled Infliximab Monotherapy to Prevent Recurrence of Crohn's Disease Following Ileocolic or Ileal Resection: A 3-year Prospective Randomized Open Trial

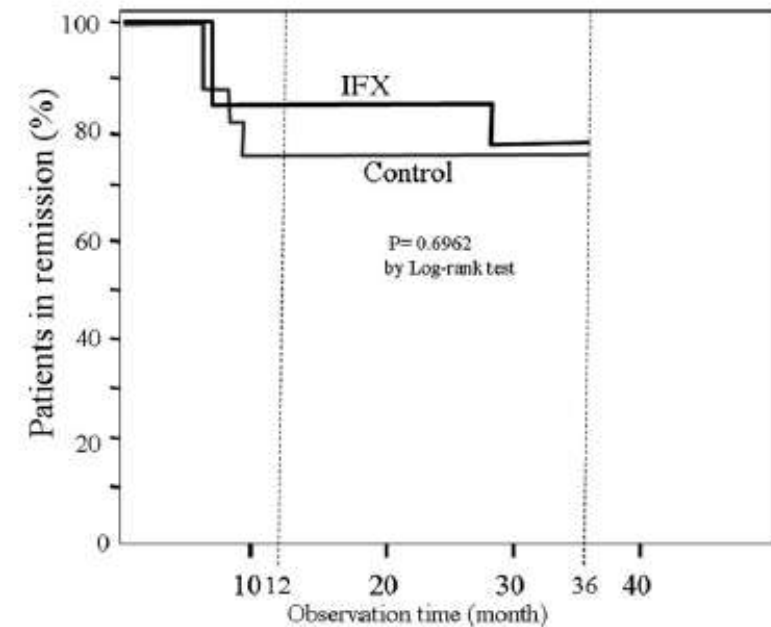


FIGURE 1. The overall 36-month survival analyses ( $n = 31$ ). The probability of avoiding relapse (%AR) did not show a significant difference at 12 months between the two arms, although the IFX arm tended to be better than the control arm.

