

Two randomized, double-blind placebo controlled trials. Patients with moderate-severe UC. IFX 5mg/kg or 10mg/kg weeks 0,2,6 and then e8w vs placebo
54 week study (ACT1) and 30 week study (ACT 2)

Primary outcome: Clinical response w8.

Secondary outcome: Mucosal healing, Steroid free remission w30 (ACT 1&2)& w54 (ACT1).

Clinical response:

W8 ACT 1: 69.4% (IFX5) vs 61.5% (IFX10) vs 37.2% (pbo) , $p<0.001$ for both comparisons.

W8 ACT2: 64.5% (IFX5) vs 69.2% (IFX10) vs 29.3% (pbo) , $p<0.001$ for both comparisons.

Mucosal healing:

W30 ACT 1: 50.4% (IFX5) vs 49.2% (IFX 10) vs 24.8% (pbo), $p<0.001$ for both comparisons.

W30 ACT 2: 46.3% (IFX5) vs 56.7% (IFX 10) vs 30.1% (pbo), $p=0.009$ & $p<0.001$

W54 ACT2: 45.5% (IFX 5) vs 46.7%(IFX 10) vs 18.2 (pbo), $p<0.001$ for both comparisons.

Steroid free remission

W54 ACT2: 25.7% (IFX 5) vs 16.4%(IFX 10) vs 9.9 (pbo), $p=0.006$

Conclusions:

IFX better than placebo inducing and maintaining remission in mod-severe UC

