2018. SECURE

Phase 4 RCT/IFX /IBD/ Maintenance

Serum concentrations after switching from originator infliximab to the biosimilar CT-P13 in patients with quiescent inflammatory bowel disease (SECURE): an open-label, multicentre, phase 4 non-inferiority trial

Prospective, open-label, interventional, non-inferiority multicenter phase 4 trial.
UC and CD patients in clinical remission who were on IFXoriginator at least for 30 weeks were switched to CT-P13

Primary endpoints: Serum concentrations at week 16 after switch.
A non-inferiority margin of 15% was set.

Results:
- The median IFX levels was 3.6 µg/mL (IQR 1.5–5.1) at baseline and 3.6 µg/mL (IQR 1.9–5.0) at week 16 in UC
- The median IFX was 3.5 µg/mL (IQR 1.8–5.2) at baseline and 4.0 µg/mL (IQR 1.9–5.4) at week 16 in CD
- Median CRP, FCAL did not differ between week 8 and week 16

Conclusion:
Switching to CT-P13 is safe and well tolerated in patients with inflammatory bowel disease in remission.
Future trials should assess switching to CT-P13 in patients with active disease.

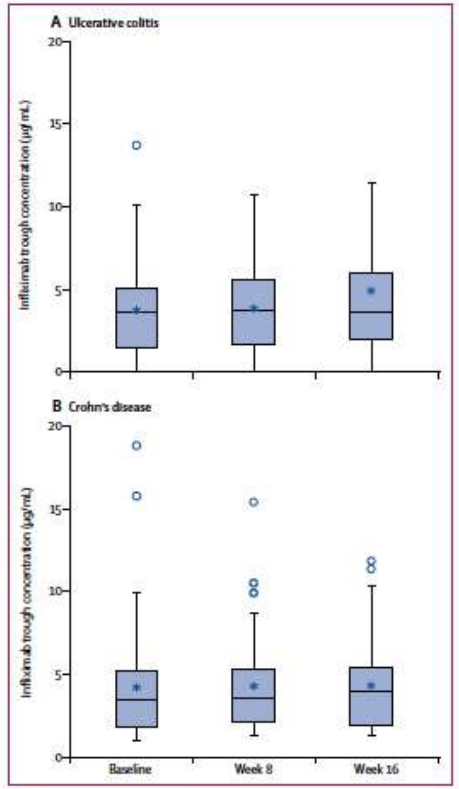

Figure 2: Infliximab serum concentrations (per-protocol population)
The box represents the IQR. The line in the middle of the box represents the median. The asterisk represents the mean. The whiskers represent the maximum (ie, 1·5 times higher than the 75th percentile) and minimum (1·5 times lower than the 25th percentile) values. The circles outside the whiskers represent outliers. (A) Patients with ulcerative colitis. One outlier of serum infliximab concentration of 52·46 mg/mL at week 16 is not shown. (B) Patients with Crohn's disease.

Strick AS et al. Lancet Gastroenterol Hepatol. 2018; 3 (6): 404-412