

Open label, randomized phase 3b controlled trial.
 Comparing treat to target (T2T) vs SoC (standard of Care) in CD with UST.
 Endoscopy w16/FC/CRP/CDAI to guide dose interval in T2T
 Treatment adjustment interval shortening: q12w→q8w// q8w→q4w//
 q4w→exit

Primary endpoint: clinical response w48

Secondary endpoints: CDAI reduction, clinical remission w48, biomarker response.

Results:

More treatment adjustment in T2T but does not improve endoscopic response at w48 compared to SoC

- SES-CD reduction: 37.7% T2T vs 29.9% SoC → p=ns
- Clinical response w48: 68.2% T2T vs 77.8% SoC; p<0.05
- Biomarker responses in T2T vs SoC regarding improvement ≥50%:
 - FC 39.4% T2T vs 46.5% SoC; p=ns
 - CRP 47.1% T2T vs 53.3% SoC; p=0.032

No new safety signals reported.

Conclusions:

Ustekinumab standard of care better than treat to target to achieve clinical response at w48.

