

Randomized, parallel-group, open-label phase 4 clinical trial. Patients with immune-mediated diseases including (rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, UC,CD or psoriasis) who were on infliximab maintenance were randomized to proactive therapeutic drug monitoring (TDM) vs standard of care (SOC).
*Patients were not necessarily in remission

Primary endpoint: Sustained disease control without disease worsening (defined by disease-specific composite scores or consensus about disease worsening between patient & physician leading to a major change in therapy)

Results: N=458

- Sustained disease control without disease worsening: 73.6% TDM vs 55.9% SOC 55.9%, $p < 0.001$
- No differences in adverse events reported between groups

Conclusion:

Among patients with immune-mediated inflammatory diseases undergoing maintenance therapy with infliximab, proactive TDM was more effective than treatment without TDM in sustaining disease control without disease worsening.

Effect of Therapeutic Drug Monitoring vs Standard Therapy During Maintenance Infliximab Therapy on Disease Control in Patients With Immune-Mediated Inflammatory Diseases A Randomized Clinical Trial

Figure 2. Sustained Disease Control With No Disease Worsening (Primary Outcome)

