2021. NOR-DRUM B RCT/IFX TDM/IMIDS/ Maintenance

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

<u>Primary endpoint:</u> 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)

	Sustained disease control, No./total (%)				
	Therapeutic drug monitoring	Standard therapy	Adjusted difference, % (95% CI)	Favors standard therapy	Favors therapeutic drug monitoring
Spondyloarthritis	54/68 (79.4)	41/70 (58.6)	20.9 (6.0 to 35.8)		
Ulcerative colitis	27/38 (71.1)	21/43 (48.8)	22.3 (1.6 to 43.1)		
Rheumatoid arthritis	27/39 (69.2)	22/40 (55.0)	13.6 (-7.4 to 34.6)		
Crohn disease	24/34 (70.6)	17/32 (53.1)	17.4 (-5.5 to 40.3)	· · · · · · · · · · · · · · · · · · ·	
Psoriatic arthritis	19/28 (67.9)	16/25 (64.0)	6.2 (-19.5 to 31.9)		•
Psoriasis	16/20 (80.0)	10/17 (58.8)	19.9 (-9.1 to 48.9)		
Overall	167/227 (73.6)	127/227 (55.9)	17.6 (9.0 to 26.2)		
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