2021. NOR-DRUM A

RCT/IFX TDM/IMIDS/ Induction

Effect of Therapeutic Drug Monitoring vs Standard Therapy During Infliximab Induction on Disease Remission in Patients With Chronic Immune-Mediated Inflammatory Diseases

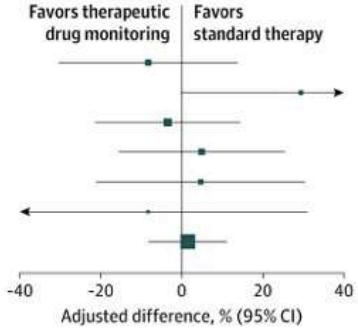
Randomized, parallel-group, open-label phase 4 superiority study. Patients with immune-mediated diseases including (rheumatoid arthritis, spondyloartrhitis, psoriatic arthritis, UC,CD or psoriaris) who were initiating infliximab were randomized to proactive therapeutic drug monitoring (TDM) vs standard of care (SOC).
*SOC arm: patients received 5mg/kg (0,2,6 and q8w thereafter) dose adjustments were considered according to clinical parameters.
*TDM arm: levels and antibodies were done prior to each infusion and dose adjusted either increasing or decreasing those was done.

Primary endpoint: Clinical remission at week 30.

Results: N=411
- Clinical remission at week 30: 50.5% TDM vs 53% SOC, p=0.78
- No differences were found in adverse events among arms.

Conclusion:
Among patients with immune-mediated inflammatory diseases initiating therapy with infliximab, proactive TDM compared to standard therapy, did not significantly improve clinical remission at week 30.

Disease subgroup	Remission rate, No./total (%)		Adjusted difference, % (95% CI)
	Therapeutic drug monitoring	Standard therapy	
Rheumatoid arthritis	21/38 (55.3)	21/42 (50.0)	-8.3 (-30.4 to 13.8)
Psoriatic arthritis	5/20 (25.0)	12/22 (54.5)	29.4 (-0.2 to 59.0)
Spondyloarthritis	23/59 (39.0)	21/58 (36.2)	-3.5 (-21.4 to 14.4)
Ulcerative colitis	25/39 (64.1)	29/41 (70.7)	4.9 (-15.6 to 25.5)
Crohn disease	17/29 (58.6)	17/28 (60.7)	4.7 (-21.1 to 30.4)
Psoriasis	9/13 (69.2)	6/9 (66.7)	-8.3 (-47.7 to 31.0)
Overall	100/198 (50.5)	106/200 (53.0)	1.5 (-8.2 to 11.1)



Clinical Remission at 30 Weeks (Primary Outcome)

Syversen SW et al. JAMA. 2021. 325 (17):1744-1754