2016. DIAMOND

OL RT/ ADA+/-AZA/CD/ Efficacy/safety

DIAMOND study: Adalimumab Monotherapy and a Combination with Azathioprine for CD: A Prospective, Randomized Trial

Randomized, prospective Open label study.
AntiTNF naïve moderate to severe CD patients randomised to: ADA (160/80/40) vs ADA+AZA (25mg or 50mg/d) in CD naïve.

Primary endpoint: remission w26
Secondary endpoints: clinical response at each time and clinical response at the other time points.

Results:

- No differences mono vs combo 71.8% vs 68.1%
- Post-hoc analyses-ADA levels w26 differ between remission rates at w52.
- ADA levels w26 of 5 predictive of response. Levels <5 risk of Antibodies

Conclusions:

Clinical efficacy of the combination of ADA+AZA did not differ from ADA monotherapy in CD naïve to both medications.

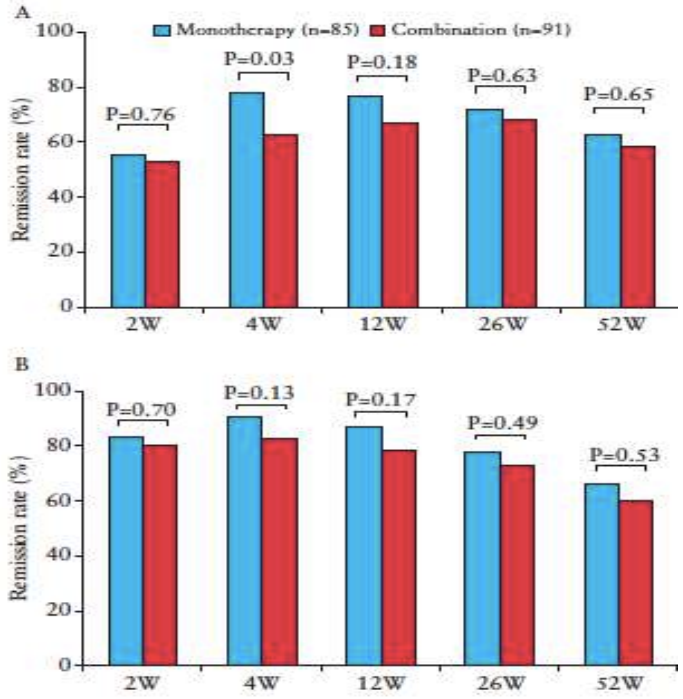

Figure 3. Rates of clinical remission [A] and clinical response [B].

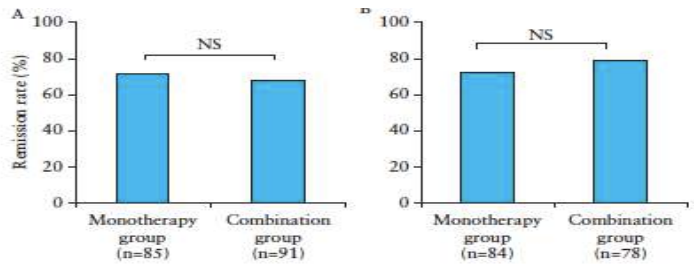

Figure 2. Comparison of clinical remission rates at Week 26. Intention-to-treat analysis with non-responder imputation [A], and per-protocol analysis, excluding patients, who discontinued the study because of side effects [B], demonstrate that the clinical remission rate did not differ between the monotherapy and combination groups.

Matsumoto T et al. J Crohn Colitis 2016; 1259-1266