2011. ULTRA I

RCT/ADA /UC/ Induction

Adalimumab for induction of clinical remission in moderately to severely active UC: results of a randomised controlled trial

8-week, randomized controlled trial.
Moderate-severe UC patients randomized to 3 arms: ADA induction 160 mg-80mg-40 mg eow, ADA 80mg at w0 and 40mg at w2,w4 and w6 or placebo.
Concomitant therapies permitted (AZA, Steroids, 5ASA)

ULTRA I Primary end point: Clinical remission w8

Results:

- Clinical remission w8 ITT: 18.5% ADA (160/80); p=0.031 vs placebo; 10% ADA (80/40); p=0.833 vs placebo, and 9.2% placebo
- Clinical response w8: 54.6% ADA (160/80) vs 51.5% ADA (80/40)vs 44.6% pbo, p=ns

Conclusions:
ADA160/80 was safe and effective for induction of clinical remission in patients with moderately to severely active UC failing treatment with corticosteroids and/or immunosuppressants.

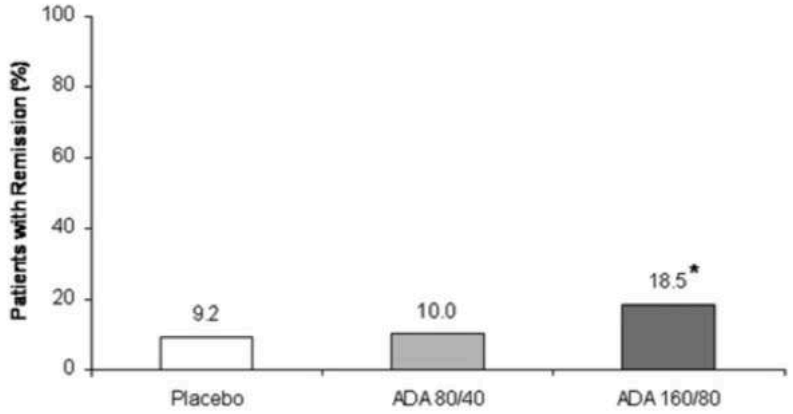

Figure 3 Clinical remission at week 8 in the ITT-A3 population (non-responder imputation). N=130 for each group. *p=0.031 versus placebo.

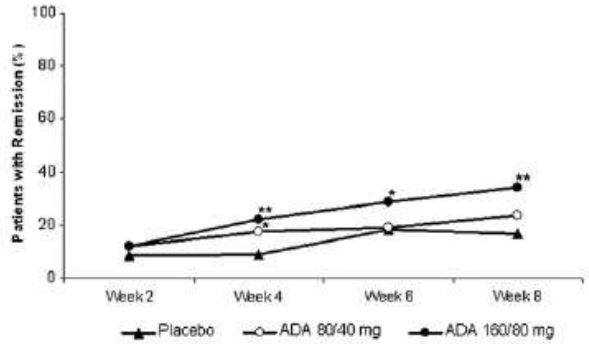

Figure 4 Clinical remission per partial Mayo score (≤2 with no subscore >1) over time in the ITT-A3 population (non-responder imputation). N=130 for each group. *p<0.05; **p<0.01 versus placebo.

Reinisch W, et al. Gut 2011;60:780–7.