2023. VEGA

RCT/Guselkumab +/-Goli/ UC/Induction

Guselkumab plus golimumab combination therapy vs guselkumab or golimumab monotherapy in patients with UC (VEGA): a randomised, double-blind, controlled, phase 2, proof-of-concept trial

Randomised, double-blind, controlled, proof-of-concept trial.
Moderate-severe active UC patients randomised to:

- Combo: Golimumab SC 200mg w0, then golimumab 100mg at w2,w4,w10 and IV guselkumab 200mg w0,,4 and 8 followed by SC guselkumab monotherapy 100mg q8w for 32w.
- Golimumab monotherapy: SC 200mg w0 and 100mg SC at w2 and q4w for 34w.
- Guselkumab monotherapy IV 200mg w0,w4,w8 followed by 100mg SC q8w for 32 w.

Primary endpoints: Clinical response at w12

Results:

- At w12 clinical response, 83% combo vs 61% golimumab (p=0.0032) vs 75% guselkumab (p=0.2155). Data efficacy endpoint was not met.
- At w12 clinical remission: 37% combo vs 22% goli (p=0.0578)vs 21% guselk (p=0.0412)
- At w12, endoscopic imprvement, endoscopic normalisation, histological remission and steroid free were higher in combo group.
- At w38 clinical response, 69% combo vs 58% goli vs 72%guselku
- At w50, 63% of combo, 76% golimumab, 65% guselkumab reported at least one adverse event.

Conclusion:
Data from this proof-of-concept study suggest that combination therapy with guselkumab and golimumab might be more effective for ulcerative colitis than therapy with either drug alone. These findings require confirmation in larger trials.

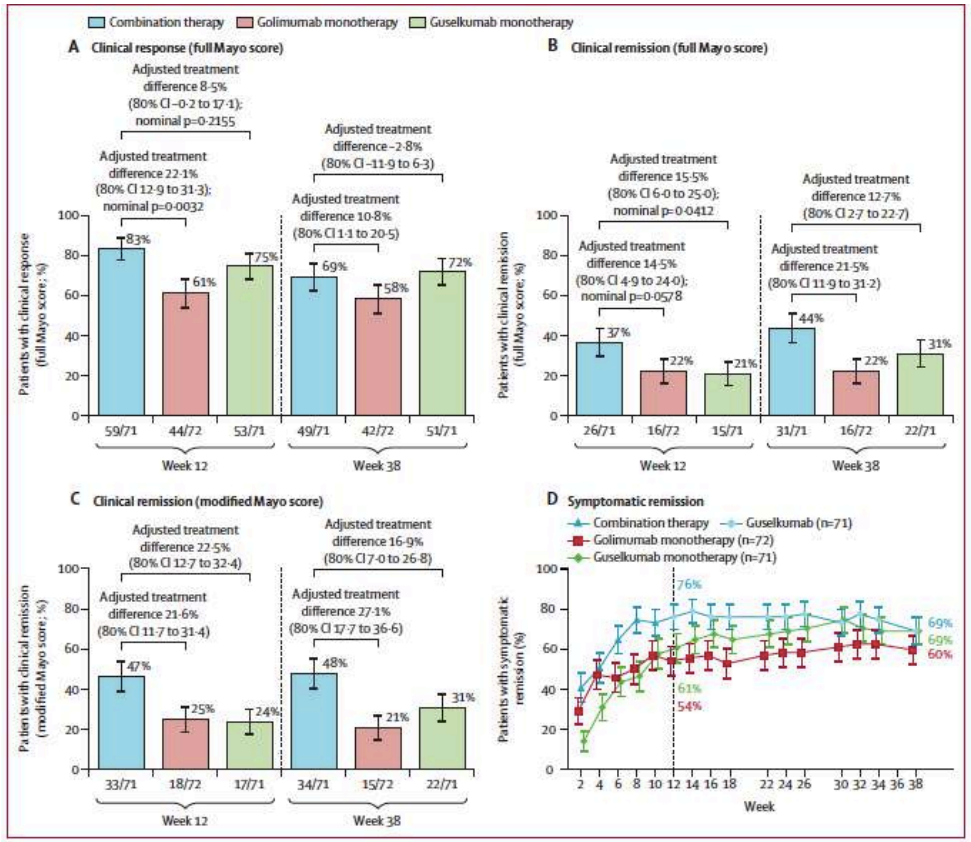

Figure 2: **Proportion of patients with clinical response and clinical remission at weeks 12 and 38 and symptomatic remission over time**
The proportion of patients who had achieved a clinical response (A) and clinical remission (B) according to the full Mayo score, and the proportion of patients who

Feagan BG et al. Lancet Gastroenterol Hepatol. 2023;