

Double-blind randomised trial. Patients who responded in the induction trials were randomised to GOLI 50 mg, GOLI 100mg or placebo q4w

Primary end point: maintenance of clinical response through w54 among golimumab-induction responders.

Secondary end points: clinical remission at both w30 and 54; mucosal healing at both w30 and 54; clinical remission at both w30 and 54 among patients who had clinical remission at PURSUIT-M baseline

Results:

- Clinical response w54 in 47.0% on 50 mg GOLI, 49.7% on 100 mg GOLI and 31.2% placebo (p=0.01 and p< .001, respectively).
- At w30 and 54, a higher percentage on 100 mg GOLI were in clinical remission and had mucosal healing (27.8% and 42.4%) than placebo (15.6% and 26.6%; p=0 .004 and p=0 .002) or 50 mg golimumab (23.2% and 41.7%, respectively).

Conclusions:

Golimumab (50 mg or 100 mg) maintained clinical response through w54 in patients who responded to induction therapy and had moderate-to-severe active UC; patients who received 100 mg had clinical remission and mucosal healing at w30 and 54.

Subcutaneous Golimumab Maintains Clinical Response in Patients With Mod-to-Severe UC

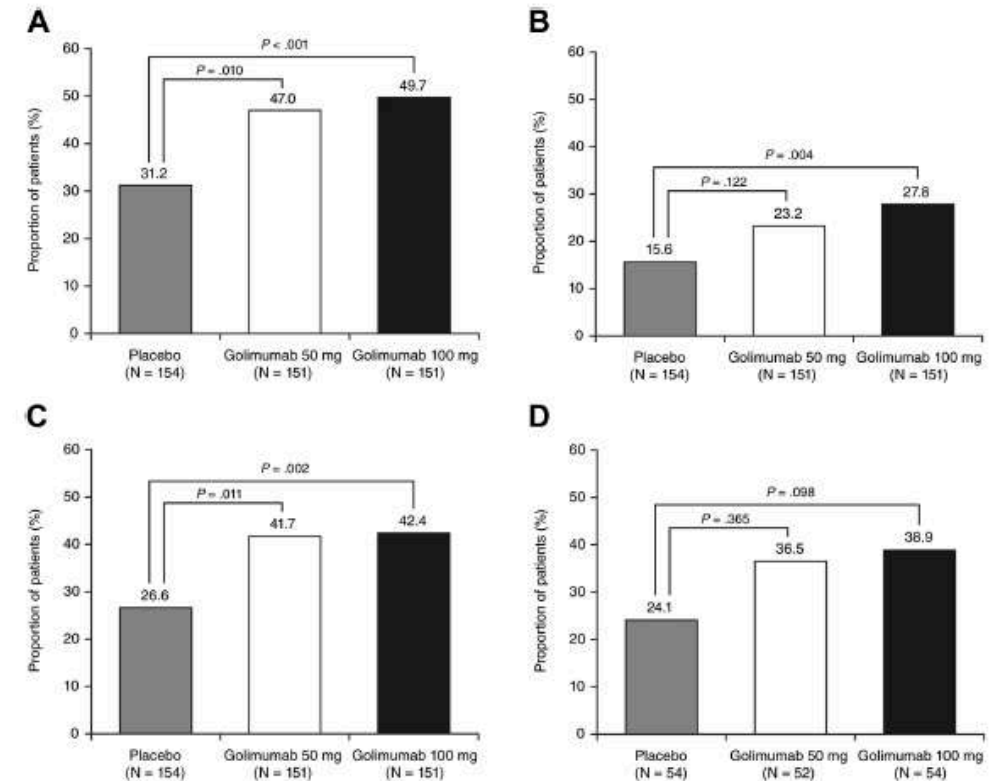


Figure 3. Proportion of golimumab-induction responders who (A) maintained clinical response through week 54; (B) achieved clinical remission at both weeks 30 and 54; (C) achieved mucosal healing at both weeks 30 and 54; (D) maintained clinical remission among those who were in clinical remission at baseline; and (E) achieved corticosteroid-free clinical remission at week 54 among those who were receiving corticosteroids at baseline. (A–E) Patients who had a prohibited change in UC medication, an ostomy or colectomy, a dose adjustment, or discontinued study agent because of a lack of therapeutic effect before the week 54 visit were considered not to have a clinical response, be in clinical remission, be in corticosteroid-free clinical remission, or have mucosal healing. (A–D) Patients who had all 4 Mayo subscores missing at weeks 30 or 54 were considered not to be in clinical response or clinical remission. Patients who had a missing endoscopy subscore at week 30 or week 54 were considered not to have mucosal healing. (E) Patients who had a missing value in corticosteroid use at a time point had their last available value carried forward to that time point. UC, ulcerative colitis.

