

OLE study that included patients who completed 26w in the PRECiSE 2 trial.

Groups:

- PRECiSE 2 continuous group: responders to certolizumab w6 of PRECiSE 2 who then received maintenance over PRECiSE 2 and PRECiSE 3;
- PRECiSE 2 drug-interruption group: responders to certolizumab w6 of PRECiSE 2 who then received placebo over 18 weeks in PRECiSE 2, followed by re-exposure to certolizumab pegol in PRECiSE 3.

Primary outcome:

Clinical response and remission at w80 & reduction in HBI score at w80

Results:

- HBI responses at w26 for the continuous and drug-interruption groups were 56.3% and 37.6%.
- Remission rates were 47.9% and 32.4%.
- Of patients responding at w26, response rates at w80 after the start of PRECiSE 2 in the continuous and drug-interruption groups were 66.1% and 63.3%, respectively.
- Among patients in remission at w26, w80 remission rates were 62.1% and 63.2%.

Conclusion:

Certolizumab pegol effectively maintains remission of Crohn's disease for up to 18 months. Continuous therapy is more effective than interrupted therapy.

Continuous Therapy With Certolizumab Pegol Maintains Remission of Patients With Crohn's Disease for up to 18 Months

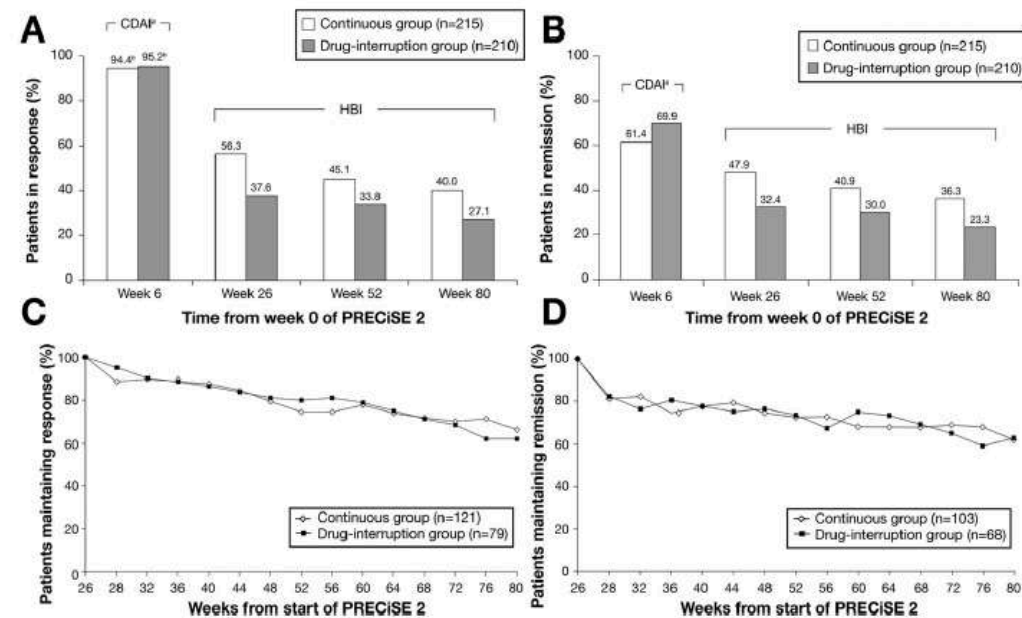


Figure 2. (A) Response rates (reduction from baseline in HBI score, ≥ 3) and (B) remission rates (HBI score, ≤ 4) in PRECiSE 2 and PRECiSE 3 at weeks 26, 52, and 80 (intention-to-treat population). (C) Sustained response and (D) remission rates in PRECiSE 3 in patients who were already in response/remission at week 26 of PRECiSE 2. ^aHBI scores were not measured at week 6 so response and remission rates for the CDAP are presented in these graphs. ^bRecalculated CDAP scores. Criterion for entry into maintenance phase of PRECiSE 2 was a CDAP response; therefore, CDAP response rate at week 6 should be 100%. However, as a result of investigator error, such as miscalculated CDAP scores and other protocol deviations, the actual CDAP response rate in the intention-to-treat population is slightly lower.

