2019. CT-P13

RCT/CT-P13 vs IFX originator/CD/Induction

Efficacy and safety of biosimilar CT-P13 compared with originator Infliximab in patients with active Crohn's disease: an international, randomised, double-blind, phase 3 non-inferiority study

Multicenter, double-blind, randomised, phase 3 non-inferiority study. Crohn's disease patients were randomized to receive CT-P13 and then CT-P13, CT-P13 and then infliximab, infliximab and then infliximab or infliximab and then CT-P13 with switching occuring at week 30.

Primary endpoints: Proportion of patients with a decrease of at least 70 points in the CDAI at week 6. Non-inferiority margin of -20%

Results:

- CDAI-70 response rates at week 6 were 69.4% CT-P13 and 74.3% IFX originator, difference -4.9 thereby not inferior.
- CDAI-70 response at week 14 and 30 were comparable between groups.

Conclusion:
This study showed non-inferiority of CT-P13 to infliximab in patients with active Crohn's disease. Biosimilar CT-P13 could be a new option for the treatment of active Crohn's disease.

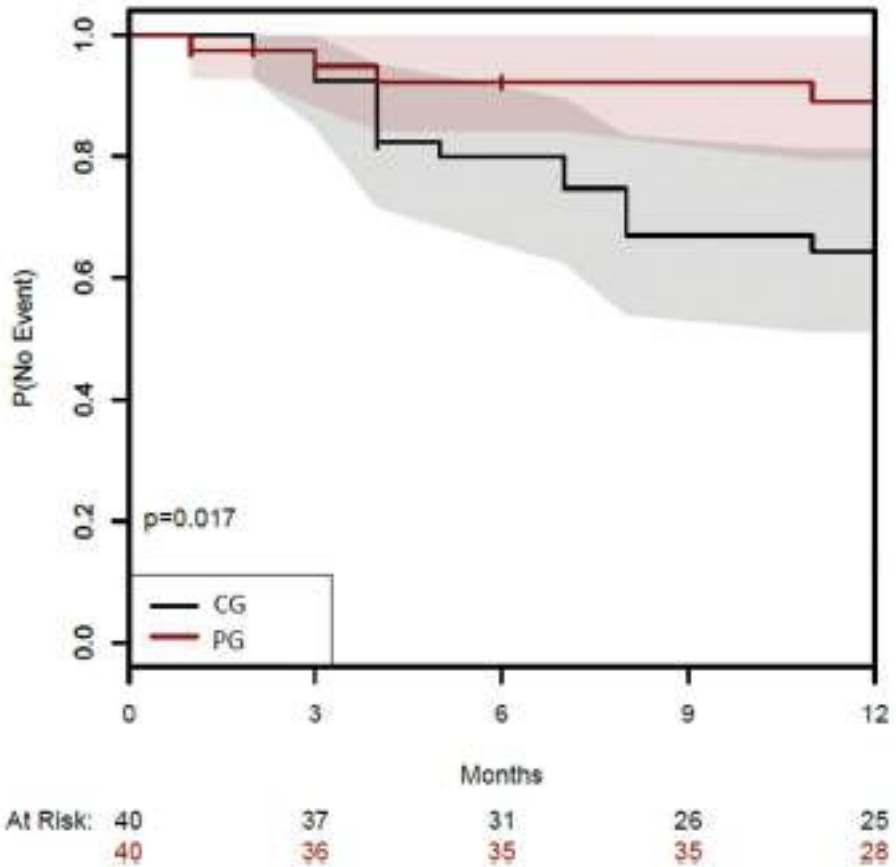

Figure 2. Kaplan–Meier curve. Proportion of patients in sustained clinical remission. Sustained clinical remission was defined as a Partial Mayo (PM) score ≤ 2 for UC or a Harvey Bradshaw Index (HBI) ≤ 4 for CD at all study visits during one year.

Ye BD et alLancet.2019; 393 (10182):1699-1707.