

Multicenter, open-label, randomized clinical trial.
Patients with CD in steroid free clinical remission >6months on combo AZA+IFX randomized to:
1)continue both; 2)stop IFX; 3) stop AZA.

Coprimary endpoints: relapse rate (superiority analysis) and time in remission over 2 years (non-inferiority analysis, non-inferiority margin 35 days).
ITT analysis

Results:

- 2 year relapse rate: 14% combo group; 36% IFX withdrawal; 10% AZA withdrawal, $p=0.003$ for IFX withdrawal vs combo and $p=0.0004$ for IFX withdrawal vs AZA withdrawal.

Conclusion:

In patients with Crohn's disease in sustained steroid-free remission under combination therapy with infliximab and immunosuppressant therapy, withdrawal of infliximab should only be considered after careful assessment of risks and benefits for each patient, whereas withdrawal of immunosuppressant therapy could generally represent a preferable strategy when considering treatment de-escalation.

Withdrawal of infliximab or concomitant immunosuppressant therapy in patients with Crohn's disease on combination therapy (SPARE): a multicentre, open-label, randomised controlled trial

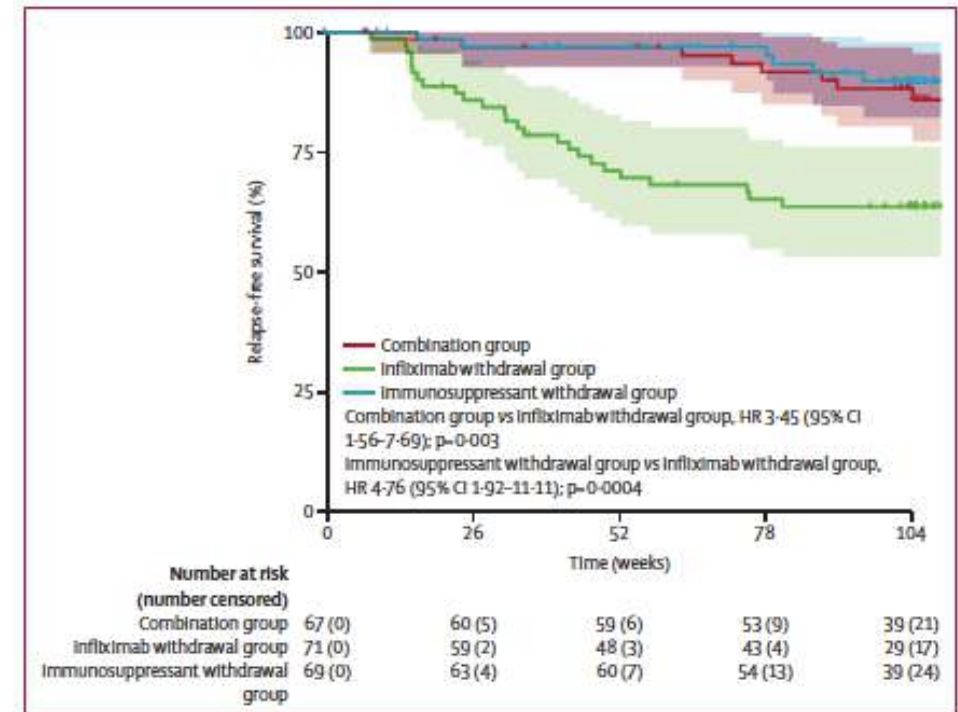


Figure 3: Relapse-free survival

Relapse-free survival was estimated by Kaplan-Meier estimators with their 95% CIs in the three groups, over 104 weeks.