

Parallel group, randomised, multicenter, clinical trial. Adult patients with refractory CD and impaired quality of life no amenable to surgery underwent stem cell mobilization and then were randomized to immunoablation and hematopoietic stem cell transplantation (HSCT) or control treatment (HSCT deferred for 1 year)

**Primary endpoints:** Sustained remission at 1 year which was a composite of clinical remission (CDAI <150), no use of steroids or immunosuppressive or biologic drugs for at least 3 months and no endoscopic or radiological evidence of active disease.

#### **Results: N=45**

- There were no differences between groups in sustained disease remission 2 (8.7%) HSCT vs 1 (4.5%) control, p=0.6
- There were 76 serious adverse events in HSCT group vs 38 in controls and one HSCT patient died.

#### **Conclusion:**

Among adult patients with refractory CD not amenable to surgery who had impaired quality of life, HSCT, compared with conventional therapy, did not result in a statistically significant improvement in sustained disease remission at 1 year and was associated with significant toxicity. These findings do not support the widespread use of HSCT for patients with refractory Crohn disease.

	No. (%)		Difference (95% CI), %	P Value
	HSCT	Control		
Sustained disease remission	2 (8.7)	1 (4.5)	4.2 (-14.2 to 22.6)	.60
Secondary outcomes				
No active treatment	14 (60.9)	5 (22.7)	38.1 (9.3 to 59.3)	.01
CDAI <150	8 (34.8)	2 (9.1)	25.7 (1.1 to 47.1)	.052
Free of active disease	8 (34.8)	2 (9.1)	25.7 (1.1 to 47.1)	.054

