

Open-label randomized controlled trial.

Patients with acute severe UC (ASUC) were randomized in 1:1 ratio to albumin + standard of care (SOC) + EEN vs. SOC + EEN

Both arms received 5 days of EEN + 400 mg IV hydrocortisone/day.

Primary endpoint: 1) steroid failure (need for rescue medical therapy or colectomy) 2) proportion of patients adverse events.

Results: N=61

- Steroid failure albumin 33.3% and SOC arm 41.94 %, p=0.49.
- No adverse events were reported with albumin infusions.
- Colectomy rate(10% vs 9.68%, P=1)
- Response to salvage medical therapy (88.89% vs 76.92%, P=0.62) and median duration of hospitalization (10.5(7-16) vs 10(7-20), P=0.43).

Conclusion:

There was no benefit of intravenous albumin infusion as an adjunct to IV steroids and EEN in patients with ASUC.

Intravenous albumin infusion does not augment the response rate to a combination of exclusive enteral nutrition and intravenous steroids in acute severe ulcerative colitis: a randomized controlled trial

	Overall	Albumin Arm (n=30)	SOC Arm (n=31)	P value	Odds ratio (95% CI)
Short term outcomes					
Steroid failure	23 (37.7 %)	10 (33.33 %)	13 (41.94 %)	0.40	0.69 (0.2-1.96)
Colectomy	6 (9.84 %)	3 (10 %)	3 (9.68 %)	1	1.04 (0.19-5.59)
Rescue medical therapy administered	N=22 IFX=6 Tofacitinib =16 Cyclosporin =1 (Also received Tofacitinib)	N=9 IFX=1 Tofacitinib=8	N=13 IFX=5 Tofacitinib=8 Cyclosporin=1 (same patient also received Tofacitinib later)		
Response to rescue medical therapy N=22	18 (81.82 %)	8 (88.89 %)	10 (76.92 %)	0.62	0.15 (0.23-0.996)
Duration of Hospitalization (days)	10 (7-16.5)	10.5 (7-16)	10 (7-20)	0.43	

