2018. Indigo naturalis

RCT/Indigo/UC/ Induction

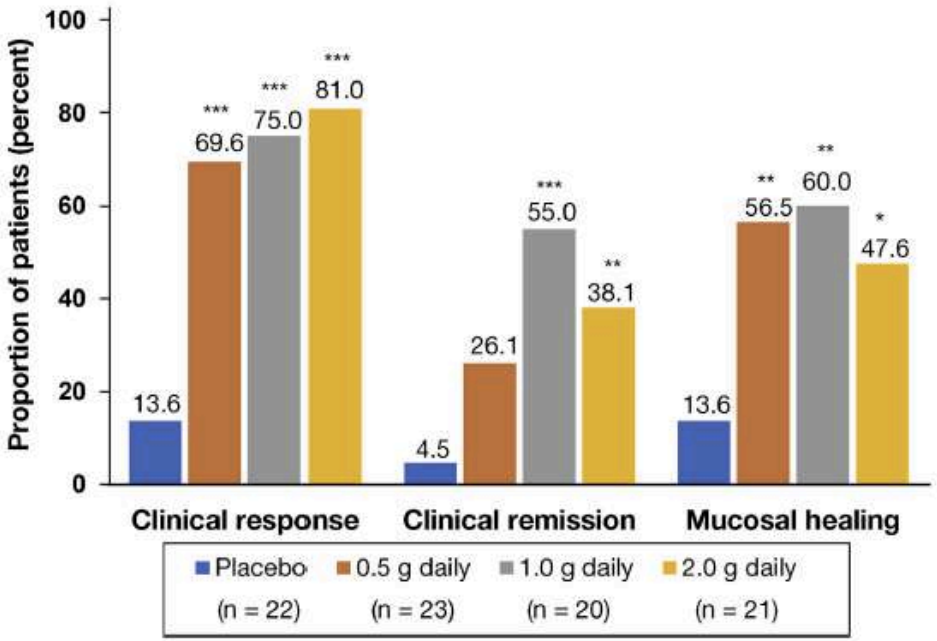
Efficacy of Indigo Naturalis in a Multicenter Randomized Controlled Trial of Patients With Ulcerative Colitis

Multicenter, double-blind, placebo controlled trial.
Adult patients with UC were randomized to indigo naturalis (IN) dose of 0.5g/da; 1 gr/d; 2 gr/day or placebo for 8 weeks.

Primary endpoint: clinical response at week 8
Defined as a 3-point decrease in the Mayo score & a decrease of at least 30% from baseline, with a decrease of at least 1 point for the rectal bleeding subscore or absolute rectal bleeding score of 0–1.

Results: N=86*

- ITT analysis, dose-dependent linear trend in clinical response was observed: 13.6% placebo; 69.6% 0.5g IN; 75% 1gIN; 81% 2gIN, p<0.0001 compared to placebo.
- Clinical remission at week 8: 4.5%placebo; 26.1% 0.5gIN (p=ns) 55% 1gIN (p=0.004) & 38.1% 2gIN (p=0.004 & 0.0093)
- Mucosal healing at week 8: 15.6% placebo, 56.5% 0.5gIN, 60% 1gIN; 47.6% 2gIN
- Mild liver dysfunction observed in 10 patients on IN



Conclusion:
8 weeks of IN (0.5–2.0 g per day) to be effective in inducing a clinical response in patients with UC.

*The trial was terminated due to a report of pulmonay arterial hypertension in a patient who self-purchased indigo for 6 months

Naganuma M et al. Gastroenterology. 2018; 154:935-947