

Pilot clinical trial.

Children with mod-severe CD were randomized to naltrexone (0.1mg/kg) orally or placebo for 8 weeks, followed by open-label treatment with additional 8 weeks of naltrexone.

Primary endpoint: Safety and toxicity of administering naltrexone in children by measuring laboratory parameters and recording any potential side effects

Results: N=14

- Oral naltrexone was well tolerated.
- PCDAI scores at w8 decreased (34.2 ± 3.3) with an 8-week course of naltrexone therapy (21.7 ± 3.9), $p=0.005$
- Clinical remission w8 25% naltrexone a
- Systemic and social quality of life improved with naltrexone treatment ($P=0.035$).

Conclusion:

Naltrexone therapy seems safe with limited toxicity when given to children with Crohn's disease and may reduce disease activity.

