

## INFLAMMATORY BOWEL DISEASE

## Low-Dose Naltrexone Therapy Improves Active Crohn's Disease

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### Abstract

#### OBJECTIVES

Endogenous opioids and opioid antagonists have been shown to play a role in healing and repair of tissues. In an open-labeled pilot prospective trial, the safety and efficacy of low-dose naltrexone (LDN), an opioid antagonist, were tested in patients with active Crohn's disease.

#### METHODS

Eligible subjects with histologically and endoscopically confirmed active Crohn's disease activity index (CDAI) score of 220–450 were enrolled in a study using 4.5 mg naltrexone/day. Infliximab was not allowed for a minimum of 8 wk prior to study initiation. Other therapy for Crohn's disease that was at a stable dose for 4 wk prior to enrollment was continued at the same doses. Patients completed the inflammatory bowel disease questionnaire (IBDQ) and the short-form (SF-36) quality of life surveys and CDAI scores were assessed pretreatment, every 4 wk on therapy and 4 wk after completion of the study drug. Drug was administered by mouth each evening for a 12-wk period.

#### RESULTS

Seventeen patients with a mean CDAI score of  $356 \pm 27$  were enrolled. CDAI scores decreased significantly ( $P = 0.01$ ) with LDN, and remained lower than baseline 4 wk after completing therapy. Eighty-nine percent of patients exhibited a response to therapy and 67% achieved a remission ( $P < 0.001$ ). Improvement was recorded in both quality of life surveys with LDN compared with baseline. No laboratory abnormalities were noted. The most common side effect was sleep disturbances, occurring in seven patients.

#### CONCLUSIONS

LDN therapy appears effective and safe in subjects with active Crohn's disease. Further studies are needed to explore the use of this compound.

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