

**NEW ULCERATIVE
COLITIS TREATMENT**

Oral colon-release parnaparin sodium tablets are safe and effective as an adjunctive therapy to aminosalicylates in patients with ulcerative colitis, according to a recently published clinical trial.

Limitations of the current medical therapy for ulcerative colitis have led to interest in new treatments including low molecular weight heparins, such as parnaparin sodium, to induce remission and prevent relapse of the disease. Previous studies have shown that parnaparin sodium, when delivered directly into a rat colon by catheter or administered orally to humans as a colon-release tablet, has an anti-inflammatory effect in the colon and is a suitable treatment for ulcerative colitis.

Giuseppe Celasco and his colleagues did a double-blind, randomized, placebo-controlled phase IIa trial to test the efficacy and safety of oral parnaparin sodium colon-release tablets when administered as an adjunct to treatment with aminosalicylates in patients with active left-sided ulcerative colitis. The researchers randomly assigned 141 participants to two groups and over an 8-week period, half received 210 mg of oral parnaparin sodium colon-release tablets whilst the remainder acted as a control and received placebo tablets. 84% of the treatment group achieved clinical remission, compared with 64% in the control group, and a higher proportion of patients in the treatment group showed clinical improvement, including disappearance of blood from stools and mucosal healing compared with control patients. Furthermore, the combination treatment was well tolerated and no serious adverse effects, bleeding complications or differences in the treatment-emergent adverse effects were reported. "Based on these promising results and the reassuring safety profile, we are planning additional phase II and III clinical trials," adds Matteo Surace, corresponding author on the study.

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Original article Celasco, G. *et al.* Clinical trial: oral colon-release parnaparin sodium tablets (CB-01-05 MMX®) for active left-sided ulcerative colitis. *Aliment. Pharmacol. Ther.* **31**, 375–386 (2010)