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*J Gastroenterol Hepatol.* 2007 Dec;22(12):2266-72. Epub 2007 Jun 7.

## Efficacy of dioctahedral smectite in treating patients of diarrhea-predominant irritable bowel syndrome.

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### Abstract

**BACKGROUND AND AIM:** Dioctahedral smectite (DS) is natural adsorbent clay useful in treating acute diarrhea. The aim of this study was to determine DS efficacy on patients with diarrhea-predominant irritable bowel syndrome (D-IBS) in a phase III-, 8-week-randomized, double-blind, placebo-controlled trial.

**METHODS:** The 104 patients who met the D-IBS Rome II criteria were randomized to receive either DS (n = 52) or placebo (n = 52) treatment for 8 weeks (three sachets daily). The primary efficacy endpoint was the changes of the visual analog scale (VAS) score of IBS overall disorder and pain/discomfort-related symptoms after treatment on days 28 and 56, respectively. Other outcome measures included improvement of bowel movement disorders. The therapeutic global response was assessed by the patients and investigators at each visit, as was drug safety.

**RESULTS:** Both treatments diminished overall disorder at each visit ( $P < 0.01$ ), with respect to primary efficacy. This effect was further observed in DS-treated patients on day 56 ( $P = 0.0167$ ). Placebo had no effect on the VAS score of pain/discomfort at any visit, whereas DS improved this score on days 28 and 56, respectively ( $P < 0.05$ ). DS and placebo similarly diminished bowel disorders at each visit; however, only DS improved abdominal bloating ( $P < 0.01$ ). The global therapeutic responses evaluated by the patients and investigators were similarly distributed. The study drug was well tolerated during the 8-week period.

**CONCLUSION:** DS seems acceptable to treat D-IBS patients, particularly for pain-related symptoms.

PMID: 17559369 [PubMed - indexed for MEDLINE]

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