

## Rifaximin provides significant relief of irritable bowel syndrome symptoms

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Yehuda Ringel, M.D., of the University of North Carolina at Chapel Hill, is a co-author of these two studies. Credit: UNC Medical Center News Office

A pair of clinical trials, conducted in part at the University of North Carolina at Chapel Hill, found that two weeks of treatment with rifaximin provides significant relief of irritable bowel syndrome symptoms including bloating, abdominal pain and loose or watery stools.

In addition, the studies found that the benefits of treatment with <u>rifaximin</u> (brand name: Xifaxan) persisted for 10 weeks after patients stopped taking the broad-spectrum antibiotic, said Yehuda Ringel, MD, an associate professor of medicine in the UNC School of Medicine and a co-author of the studies, which are published in the Jan. 6, 2011 issue of the <u>New England Journal of Medicine</u>.

"These results support the idea that intestinal microbiota or <u>gut bacteria</u> may be an underlying cause of IBS, and altering gut bacteria by treatment with rifaximin appears to be an effective way of providing relief to those who suffer from IBS

symptoms," Dr. Ringel said.

First author of the studies is Mark Pimentel, MD of Cedars-Sinai Medical Center in Los Angeles. The corresponding author is William P. Forbes, PharmD, of Salix Pharmaceuticals of Morrisville, N.C., which makes the drug and funded the studies.

The two studies, known as TARGET 1 and TARGET 2, were conducted in parallel from June 2008 through June 2009. In the studies, a total of 1,260 patients who had <u>irritable bowel syndrome</u> (IBS) without constipation were enrolled at one of 179 study sites in the U.S. and Canada. All were randomized to receive the study drug in 550 milligram doses, three times daily for two weeks, or placebo. All were then followed for an additional 10 weeks.

During the first four weeks after treatment, 40.7 percent of the patients in the rifaximin group reported adequate relief of global IBS symptoms, compared to 31.7 percent in the placebo group. Similarly, 40.2 percent in the rifaximin group had adequate relief of bloating, compared to 30.3 percent on placebo. Also, significantly more patients taking the study drug reported adequate reductions of abdominal pain and loose or watery stools.

The studies concluded that taking 550 milligram doses of rifaximin three times a day for 14 days provides better relief of IBS symptoms than placebo for up to 10 weeks after completion of therapy.

Dr. Ringel added that rifaximin, which is a semisynthetic antibiotic, has additional advantages including low systemic absorption (more than 99 percent is secreted in the stool), good antibacterial activity, low microbial resistance and a high safety profile.

"These studies support the idea that gut bacteria



have an important role in maintaining normal intestinal function and emphasize the need for further research on the interaction between the intestinal microbiota and the human host," Dr. Ringel said.

Additional studies currently under way at UNC are aimed at providing a better understanding of the mechanisms by which changes in the composition of the intestinal microbiota can alter intestinal function and lead to gastrointestinal symptoms, Dr. Ringel said.

Provided by University of North Carolina School of Medicine

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