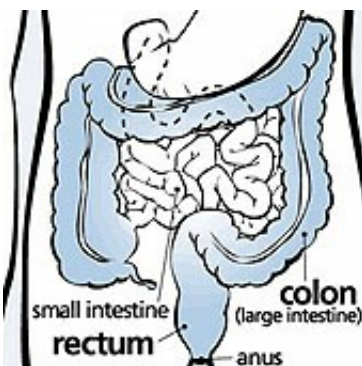


New drug might help treat irritable bowel syndrome

September 18 2012, by Amanda Gardner, Healthday Reporter



Maker-funded studies found reduction in symptoms such as abdominal pain.

(HealthDay)—A new drug significantly reduces the abdominal pain and constipation characteristic of certain types of irritable bowel syndrome, according to two new studies.

Both [phase 3](#) trials, published online Sept. 18 in the [American Journal of Gastroenterology](#), formed much of the basis for approval of the drug, Linzess (linaclotide), by the U.S. [Food and Drug Administration](#) in August, said Dr. William Chey, lead author of one of the studies and co-editor-in-chief of the journal.

"These are as good a set of results as we've seen on a drug for patients with constipation-predominant irritable bowel syndrome," said Chey, who is a professor of medicine at the University of Michigan Health

System, in Ann Arbor.

Both trials were funded by Forest Research Institute and Ironwood Pharmaceuticals, Inc., which make the drug. An Ironwood employee provided editorial assistance for both studies.

Irritable bowel syndrome is a difficult-to-diagnose and difficult-to-treat condition that can have paradoxically opposite symptoms.

Although patients with irritable bowel syndrome universally complain of [abdominal pain](#) and discomfort, this can be due either to diarrhea or constipation or a combination, Chey said.

No one knows exactly what causes the condition (and it may be more than one condition) so a diagnosis is made based on symptoms.

Until the approval of Linzess, only two drugs were approved for the condition, one for constipation-predominant irritable bowel syndrome and one for diarrhea-predominant irritable bowel syndrome, Chey said.

And roughly half of patients don't have adequate [symptom relief](#) with [prescription drugs](#), over-the-counter medications or [dietary changes](#), he added.

The trial led by Chey involved 804 adults, mostly women, who were randomly assigned to receive 290 [micrograms](#) of Linzess or an inactive placebo once a day for six months.

Several outcomes were measured but the most rigorous was one stipulated by the FDA: that the patient reported an improvement of at least 30 percent in abdominal pain and an increase of at least one bowel movement each week for six to 12 weeks, among other gauges.

About one-third of participants taking Linzess experienced the FDA-specified improvements, including less pain and increased bowel movements, versus 14 percent of those in the placebo group, the investigators found.

On average, participants reported about 43 percent improvement in abdominal pain by the end of the treatment period, along with easing of other symptoms such as cramping and bloating. The improvements started almost right away.

The second trial looked at 800 patients randomly assigned to the same dose of Linzess or a placebo, this time for 12 weeks. Again, about one-third of patients taking Linzess reported improvements in pain and constipation versus 21 percent in the placebo group.

When patients were later switched from linaclotide to a placebo, their symptoms returned, the researchers found.

The main side effect was [diarrhea](#), the study authors, led by Dr. Satish Rao, of Georgia Health Sciences University in Augusta, noted in the report.

Linzess is believed to work by stimulating the secretion of chloride and water in the intestine. This helps soften the stool and stimulate contractions that can lead to bowel movements, they explained.

Commenting on the research, Dr. Timothy Pfanner, a gastroenterologist and assistant professor of internal medicine at Texas A&M Health Science Center College of Medicine, said: "This is a really interesting drug in that it works differently than anything else we have. It basically acts on some nerve receptors and stimulates them to inhibit the pain response and reduces bloating and increases motility," he added.

"There are lots of drugs out there for constipation," Pfanner noted. "What makes this different is it may actually help with the irritable bowel-type symptoms, particularly bloating and pain. That's a real advantage."

Unlike inflammatory bowel disease—which includes Crohn's disease and ulcerative colitis—biopsies reveal no abnormalities in the colons of people with [irritable bowel syndrome](#). In inflammatory bowel disease, biopsies show "all kinds of inflammation," Pfanner said. "The colon looks angry and red and swollen."

Although a price hasn't been set for Linzess, a similar existing [drug](#) costs patients roughly \$200 to \$300 per month.

More information: The U.S. National Library of Medicine has more about [irritable bowel syndrome](#).

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