

New drug for Crohn's disease shows early promise

19 March 2015, by Amy Norton, Healthday Reporter



But findings are preliminary, experts point out.

(HealthDay)—An experimental drug may quickly quash symptoms of the digestive disorder Crohn's disease—at least for the short term, an early clinical trial finds.

The study, of more than 150 adults with Crohn's, found that just two weeks of treatment sent many into remission—meaning they had few to no symptoms of the [inflammatory bowel disease](#) 28 days after the study began.

Experts said the findings are encouraging. For one, the drug is a pill, whereas the current "biologic" drugs for Crohn's—such as Remicade and Humira—are given by injection or IV.

And the drug worked quickly. "There was a pretty high remission rate in a short period of time. That's impressive," said Dr. Raymond Cross, a gastroenterologist at the University of Maryland Medical Center, who was not involved in the study.

In theory, the new drug—dubbed mongersen—could be safer than existing medications, too, according to Cross. Cross also co-chairs the education committee for the Crohn's & Colitis Foundation of America (CCFA).

But time will tell, Cross said. "You can't really assess safety in two weeks," he explained.

And, the study authors wrote that longer-term studies of both the safety and effectiveness of mongersen need to be done, along with studies that compare the new drug to existing therapies.

Results of the study were published March 19 in the *New England Journal of Medicine*. The trial was funded by Giuliani (an Italian pharmaceutical company), under contract to Nogra Pharma—a Dublin, Ireland, company that developed mongersen. Nogra Pharma recently struck a licensing agreement with U.S.-based Celgene Corp. to market the drug.

According to the CCFA, up to 700,000 Americans have Crohn's—a chronic inflammatory disease that causes abdominal cramps, diarrhea, constipation and rectal bleeding. It arises when the immune system mistakenly attacks the lining of the digestive tract.

There are already a number of drugs that work well against Crohn's, Cross said—particularly the biologics, which block specific proteins that trigger the inflammation in Crohn's.

But the existing medications don't work for everyone, Cross explained. And with biologics, he said, some people who do well at first eventually develop antibodies against the drugs.

The medications can also have side effects. Those include infections and other immune-related diseases, such as the skin condition psoriasis, said Dr. Giovanni Monteleone, the lead researcher on the new study and a [gastroenterologist](#) at the University of Rome Tor Vergata, in Italy.

The "advantage" with mongersen is that it's taken orally, which allows "maximal release" of the active compound to inflamed sites in the digestive tract, Monteleone said. The drug works by restoring the natural activity of an anti-inflammatory protein called TGF-beta, he explained.

For the current study, Monteleone's team randomly assigned 166 Crohn's patients to one of four groups: three that received different daily doses of mongersen for two weeks; and one that was given placebo (inactive) pills for comparison.

By the end of treatment, two-thirds of patients on the highest drug dose had gone into remission. The same was true for 55 percent of those on the next-highest dose.

As for adverse events, the researchers reported, most were related to the disease itself—including worsening [symptoms](#) among patients on the lowest drug dose.

According to Cross, it's possible that with mongersen's mode of action, the drug could avoid the side effects of existing Crohn's drugs—but that's unproven for now.

Monteleone said further studies are needed to figure out the optimal [drug](#) dose, and see how well it works in the longer term.

Cross agreed. "These findings are exciting, but they're preliminary," he said.

More information: The Crohn's & Colitis Foundation of America has more on [Crohn's disease](#).

New England Journal of Medicine paper:

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