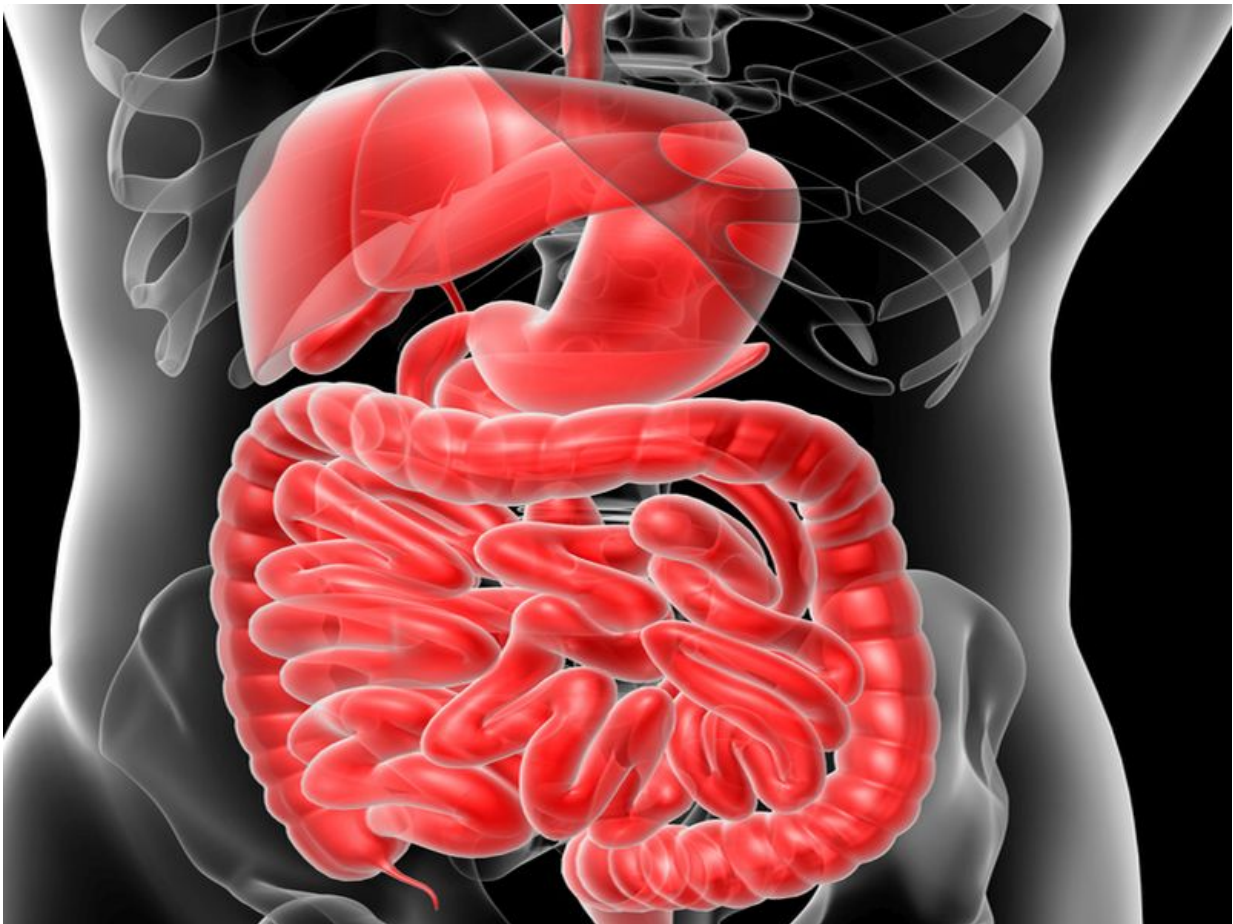


Arthritis drug shows promise for ulcerative colitis

May 3 2017, by Steven Reinberg, Healthday Reporter



(HealthDay)—A new study finds that people with moderate to severe

ulcerative colitis who haven't done well on other treatments may find relief with Xeljanz (tofacitinib), a drug currently used to treat arthritis.

Ulcerative colitis is a chronic inflammatory bowel disease. It affects about 700,000 Americans, according to the Crohn's and Colitis Foundation (CCF).

The illness causes inflammation, irritation, swelling and sores on the lining of the large intestine. Symptoms include diarrhea with blood or pus and abdominal discomfort, according to CCF.

"There is still a substantial unmet need for new treatments for [patients](#) with [ulcerative colitis](#)," said study lead author Dr. William Sandborn. He is professor of medicine and chief of the division of gastroenterology at the University of California, San Diego.

Xeljanz targets certain proteins involved in the body's inflammatory and immune responses that other so-called biologic drugs don't, the researchers said.

"Treatment with oral tofacitinib is potentially a new [treatment](#) option for patients with moderate to severe ulcerative colitis, pending review by the [U.S. Food and Drug Administration]," Sandborn said.

The study was funded by Pfizer, Inc., the maker of Xeljanz. Sandborn said he has received research grants from the company and served as a consultant for Pfizer.

Whether Xeljanz should be used as a first treatment is still not clear, said Dr. Arun Swaminath, director of the [inflammatory bowel disease](#) program at Lenox Hill Hospital in New York City.

Because Xeljanz comes as a pill, it could have an advantage for patients,

Swaminath said. But so far it has only been tried with patients who have not responded to other treatments, he said.

"How it is used in the real world may be different than how it was used in these studies," Swaminath said. "I am not going out on a limb and say this should be the first choice, because we don't have enough data to say that's the way it should be positioned."

The researchers randomly assigned more than 1,700 people with ulcerative colitis to one of three phase 3 trials.

The first two trials looked at more than 1,100 patients with moderate to severe ulcerative colitis who had failed with conventional treatment or treatment with newer "tumor necrosis factor antagonist" drugs, such as Remicade (infliximab). They received Xeljanz or a [placebo](#) twice a day for eight weeks.

In the third trial, nearly 600 patients who responded to Xeljanz were assigned to a maintenance dose (one group with 5 milligrams [mg] and another group with 10 mg) of the drug, or placebo for a year.

In the first trial, nearly 19 percent of the patients taking Xeljanz experienced a remission of their condition in eight weeks. That compared to just 8 percent of patients receiving placebo.

In the second trial, almost 17 percent of those taking Xeljanz had a remission, compared with nearly 4 percent of those taking placebo, the researchers found.

In the third trial, more than 34 percent of patients taking 5 mg of Xeljanz had disease remission after one year. Forty percent of those taking a 10-mg dose of the drug had remission at a year. Only 11 percent of patients on placebo saw a remission.

However, in all of the trials, more patients taking Xeljanz suffered from infections, such as shingles, than those receiving placebo, researchers found.

In addition, five patients taking Xeljanz developed nonmelanoma skin cancer, compared with one patient receiving placebo. Five patients taking the drug experienced heart problems compared with no one on the placebo.

Also, compared with placebo, Xeljanz was associated with an increase in levels of cholesterol.

The report was published May 4 in the *New England Journal of Medicine*.

Dr. Sonia Friedman is an associate professor of medicine at Harvard Medical School. She's also the author of an editorial accompanying the study.

"Tofacitinib is a promising new class of medical therapy that has efficacy in ulcerative colitis. It is an oral, small-molecule [drug](#) that is different from current biologic therapies, such as infliximab [Remicade], adalimumab [Humira], golimumab [Simponi] and vedolizumab [Entyvio]," Friedman said.

An advantage of Xeljanz is that it is a pill. Other biologic drugs are given by infusion or injection. In addition, patients cannot develop antibodies to Xeljanz as they can with other [biologic drugs](#), Friedman said.

"Tofacitinib may be used in the future as rescue therapy from failure of biologics," she said. "Only future studies will determine whether it can be used as initial therapy for ulcerative colitis and what patients it would help the most."

More information: William Sandborn, M.D., professor, medicine, and chief, division of gastroenterology, University of California, San Diego; Sonia Friedman, M.D., associate professor, medicine, Harvard Medical School, Boston; Arun Swaminath, M.D., director, inflammatory bowel disease program, Lenox Hill Hospital, New York City; May 4, 2017, *New England Journal of Medicine*

For more information on ulcerative colitis, visit the [U.S. National Institute of Diabetes and Digestive and Kidney Diseases](#).

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