Experimental pill may ease multiple sclerosis disability

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Latest trial shows laquinimod can also help prevent relapse.

(HealthDay) -- Yet another orally taken medication shows some promise in preventing relapse and disability for people with relapsing-remitting multiple sclerosis, a new report suggests.

In the new study, laquinimod reduced the annual relapse rate by 23 percent, and disability progression by 36 percent.

"We found that laquinimod, as compared with placebo, reduced the rate of relapse and slowed the progression of disability in patients with relapsing-remitting multiple sclerosis," the European researchers, led by Dr. Giancarlo Comi of the Institute of Experimental Neurology in Milan, wrote.

The study, which was funded by the drug's manufacturer, Teva Pharmaceutical Industries, was published in the March 15 issue of the New England Journal of Medicine.

Multiple sclerosis (MS) is a disease that damages the outside of nerve fibers in the central nervous system, according to the National Multiple Sclerosis Society. The brain, spine and optic nerves make up the central nervous system. Symptoms of the disease can include fatigue, numbness in the limbs, balance and coordination problems, bladder or bowel dysfunction, vision problems, pain and even paralysis, according to the society.

Most patients -- about 85 percent -- have a form of MS that's called relapsing-remitting, the society has reported. That means that people have periods where the disease is very active, and at other times the disease remits. During these periods of remission, there may be complete or partial recovery of function, and the disease doesn't progress during remission, according to the society.

All of the more than 1,100 people included in the current study had relapsing-remitting MS; the volunteers came from 139 sites in 24 countries. They were randomly assigned to receive a laquinimod pill or an inactive placebo once daily for 24 months.

The annual relapse rate for those on the active drug was 0.30 compared to 0.39 for those on a placebo, a reduction in relapse of 23 percent for those on the medication. During the study, 63 percent of those on the drug remained relapse-free compared to 52 percent of those on placebo.

Just over 11 percent of those taking laquinimod had confirmed disability progression compared to 15.7 percent of those on placebo, the researchers found.

The drug was generally well-tolerated. The most significant side effects appeared to be urinary tract infections and a temporary abnormality in liver function tests.

This isn't the first pill developed for MS. The first was Gilenya, which was approved in 2010 for the treatment of relapsing-remitting MS. This drug is currently under increased scrutiny in the United States and Europe because there have been 11 unexpected deaths in people taking the drug. Several other oral medications are in development. One is called teriflunomide, and it's also for the treatment of relapsing-remitting MS; its manufacturer recently filed for approval in the United States and Europe. Before Gilenya was approved, MS medications had to be given by injection.

"This is meaningful because it's a more convenient way of taking medication. I don't think it will differ significantly in efficacy from other agents. The safety data looks good now, but many low-frequency side effects only become apparent [after a drug has been approved] in post-marketing trials," said Dr. Malcolm Gottesman, chief of the division of neurology, co-director of neuroscience and director of the Winthrop Comprehensive MS Care Center at Winthrop University Hospital in Mineola, N.Y.

"Right now, it looks good. It looks like it works and is easy to take," Gottesman said, adding that it's not going to be a groundbreaking change in treatment.

Timothy Coetzee, chief research officer for the MS society, said laquinimod works differently than the other pills and looks as if it might have some protective effects that other drugs don't offer, though more research is needed into that potential aspect.

He said it's not clear if laquinimod's modest effect on relapse rates is

"clinically meaningful," which means, does it make a difference to someone living with MS? He said that if the manufacturer files for U.S. Food and Drug Administration approval, "regulators are looking for a clinically meaningful impact."

But, Coetzee added, "This study illustrates that there are oral agents becoming available for people with MS. And, it brings hope that we will have a next generation of agents, and that we can hopefully stop the progression of MS."

More information: Learn more about multiple sclerosis from the National Multiple Sclerosis Society.

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