

Experimental drug shows promise for genital herpes treatment

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But larger, longer trials are needed, experts say.

(HealthDay)—An experimental drug could eventually offer a new treatment option for genital herpes, a common and incurable sexually transmitted infection, researchers report.

In a small study, researchers found that the drug—called pritelivir—substantially curbed "viral shedding" in people with genital herpes. That means it decreased the amount of time the virus was active and potentially transmissible to patients' sexual partners.

The findings, reported in the Jan. 16 issue of the *New England Journal of Medicine*, are based on 156 patients followed for just four weeks. Experts cautioned that the study is preliminary and offers a "proof of concept."



Still, they said, the results are important because pritelivir is the first in a new class of drugs that works differently than existing medications for genital herpes. The hope is that pritelivir will be better at preventing transmission of the virus.

"There was a fairly dramatic decrease in the probability of viral shedding in this study," said Dr. Richard Whitley, an infectious disease expert at the University of Alabama at Birmingham.

There is still a lot of research to be done, said Whitley, who wrote an editorial published with the study. But he said it's good news that drugs that work in new ways are under development.

"We're at the beginning of a new era" in genital herpes treatment, Whitley said.

Genital herpes is caused by the <u>herpes simplex virus</u>—usually the strain known as HSV-2. It's a common disease: An estimated 16 percent of Americans aged 14 to 49 have an HSV-2 infection, according to the U.S. Centers for Disease Control and Prevention.

The infection may cause painful sores around the genitals, rectum or mouth. But, more often, it causes no symptoms or only mild ones, which means most people with HSV are unaware they're infected.

HSV can be dangerous, however. If it's passed from a mother to a newborn, the infection can be fatal. In rare cases, HSV invades the brain and triggers potentially deadly inflammation.

There is no cure for genital herpes. Once a person is infected, HSV hides out in nerve cells and reactivates periodically—sometimes causing symptoms, sometimes not. Currently, three medications can treat symptoms, and—if taken daily—suppress new symptom outbreaks:



acyclovir (brand name Zovirax), famciclovir (Famvir) and valacyclovir (Valtrex).

Even with that daily treatment, there is still viral shedding and the drugs cut HSV transmission by only about half, said Dr. Anna Wald, lead researcher on the new study.

"Clearly, we'd like to do better," said Wald, a professor of allergy and infectious disease at the University of Washington, in Seattle.

Acyclovir, the oldest of the existing drugs, was developed in the 1980s. All three medications had a big impact on managing genital herpes when they came out, said Dr. Lawrence Stanberry, an infectious disease expert at Columbia University Medical Center/NewYork-Presbyterian Hospital, in New York City.

Stanberry agreed, however, that the drugs fall short when it comes to preventing HSV transmission. Plus, he said, doctors are seeing some viral resistance to acyclovir in patients with compromised immune systems, such as people with HIV.

The ultimate hope is to develop drugs that eliminate dormant HSV from the <u>nerve cells</u>, said Stanberry, who was not involved in the new study.

"But we don't have anything like that," he said. "And [pritelivir] is not it either."

"[But] it's exciting that there's a new class of drugs," Stanberry said.
"This has the potential to improve treatment."

The study, funded by German drug maker AiCuris, included 156 adults with HSV-2 infections. They were randomly assigned to one of five groups. One group received placebo pills, while the other four took



different doses of pritelivir.

Over 28 days, patients on the highest drug dose (75 milligrams a day) showed the biggest effects. They had viral shedding on only 2 percent of those days, versus almost 17 percent in the placebo group. Another group, which received a once-a-week 400 mg dose, also showed a significant drop in viral shedding.

That's important, Stanberry said, because if a once-weekly drug dose were effective, that would make treatment more convenient.

There were no significant side effects from the medication, according to the researchers. But, Ward said, the study was small and short-term, so the safety question needs more investigation.

Further clinical trials of the drug are on hold right now. Last May, the U.S. Food and Drug Administration suspended the work after research in monkeys showed some unexpected blood and skin abnormalities.

It's not clear why, Ward said. "We haven't seen those effects in humans," she said.

More information: The U.S. Centers for Disease Control and Prevention has more on genital herpes.

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