Experimental pill may fight antibioticresistant UTIs

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<u>Urinary tract infections</u> are common and usually simple to treat. But for

people who become sick enough to land in the hospital with one, an experimental antibiotic may soon offer a new treatment option—taken by mouth instead of delivered by IV.

In a clinical trial, researchers found that the pill, called tebipenem HBr, worked as well as a standard IV antibiotic in treating patients hospitalized with "complicated" UTIs. That included people infected with bacteria that resist many other oral antibiotics.

The drug is not yet available, but developer Spero Therapeutics announced earlier this year that the U.S. Food and Drug Administration had granted its new drug application priority review. The company said that, if approved, the oral antibiotic could potentially allow some patients to recover at home, or at least leave the hospital sooner.

If that happens, the medication would "fill a gap" in the treatment of complicated UTIs, said an infectious diseases expert who was not involved in the trial.

The drug's "real value" would be for patients with UTIs caused by bacterial strains that are highly resistant to common oral antibiotics, said Dr. Neil Clancy, a professor of medicine at the University of Pittsburgh.

"Right now, we have many options for most UTIs, both in and out of the hospital," said Clancy, who is also a spokesperson for the Infectious Diseases Society of America.

But patients in this trial had UTIs caused by various antibiotic-resistant bacteria, including bugs that produce an enzyme called extended-spectrum beta-lactamases (ESBL). That enzyme breaks down and destroys many common antibiotics, including penicillins and cephalosporins.

ESBL-producing bacteria are a "big issue," Clancy said, noting that the bugs are listed as a <u>serious threat</u> by the U.S. Centers for Disease Control and Prevention.

A class of antibiotics called carbapenems still work well against ESBL-producing bacteria, according to the <u>CDC</u>. But those medications are given only by IV or injection.

Tebipenem HBr is also a carbapenem, but in pill form.

"Right now, we really don't have a reliable oral option [against ESBL-producing bacteria]," Clancy said. "This new agent may fill that gap."

The study, published April 7 in the *New England Journal of Medicine*, involved more than 1,300 patients in the United States, Europe and South Africa who were hospitalized for complicated UTIs.

UTIs can involve any part of the <u>urinary tract</u>, including the bladder, urethra and kidneys. While most UTIs respond quickly to <u>oral antibiotics</u>, complicated cases do not. Some people develop a serious kidney infection called <u>acute pyelonephritis</u>—which was seen in half of the study patients.

In general, Clancy said, certain <u>medical conditions</u> or anatomical abnormalities in the <u>urinary tract</u> can make people more vulnerable to complicated UTIs. Kidney disease, diabetes and pregnancy are among the risk factors.

The study patients were randomly assigned to one of two groups: One received a standard IV carbapenem, while the other received the new pill, for seven to 10 days.

In the end, the two treatments were equally effective: By day 19 of the

trial, about 93% of patients in both groups were free of UTI symptoms, or feeling better with no new symptoms. Side effects were also similar—with one-quarter of patients on either treatment having problems like mild diarrhea or headache.

Since tebipenem HBr is not yet approved, it's too soon to say whether it could become the preferred treatment over IV antibiotics, trial leader Dr. Angela Talley of Spero Therapeutics said in a company statement.

She called the trial a "first step," and said it did not address, for example, using the pill outside of the hospital.

For his part, Clancy said he thinks the antibiotic will, if approved, end up being prescribed to some outpatients. But what's critical, he stressed, is that it be "used judiciously," and only in cases where people have UTIs caused by particular treatment-resistant bacteria.

Overuse and misuse of antibiotics are among the primary reasons that bacteria are able to develop resistance to the medications. And the public health consequences are huge.

According to the CDC, over 2.8 million Americans develop antibiotic-resistant infections each year, with more than 35,000 dying as a result.

More information: The U.S. National Institutes of Health has more on <u>urinary tract infections.</u>

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