

New, long-acting drugs cut frequency of migraine headaches

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New, long-acting drugs may hold hope for millions of people who often suffer migraines. Studies of two of these medicines, given as shots every month or so, found they cut the frequency of the notoriously painful and

disabling headaches.

The drugs are the first preventive medicines developed specifically for migraines. They work by interfering with a substance involved in modifying nerve signaling and progression of pain and symptoms.

"It's a whole new direction" for treatment and an important advance for people who don't want to take or aren't helped by the daily pills sometimes used now to prevent recurrences, said Dr. Andrew Hershey, neurology chief at Cincinnati Children's Hospital Medical Center.

He had no role in the research but has tested other migraine drugs and wrote a commentary published with the studies Wednesday by the *New England Journal of Medicine*.

Migraines plague more than a billion people worldwide, more than 38 million in the U.S. alone. They're more severe than an ordinary headache - throbbing, squeezing pain and pressure, often accompanied by vision problems, sensitivity to light, noise or smells, and nausea. They can leave people unable to work or do simple things like cooking or even hold a conversation.

WHAT THE STUDIES SHOW

One study tested erenumab (er-EN-yoo-mab), from Amgen and Novartis, in about 900 people who averaged eight migraines a month. Nearly half had already tried other preventive medicines.

For six months, they were given monthly shots into the abdomen of a high dose of the drug, a low dose or a dummy medicine. The number of days they suffered migraines each month dropped by three to four in the drug groups and nearly two in the placebo group. Half of the patients on the higher dose saw their migraine days cut at least in half.

"I very definitely benefited," said Anne Vickers, who got the lower dose through one of the study leaders at Mercy Hospital St. Louis in Missouri.

"I can have anywhere from 15 to 18 headaches per month, and probably five of those days are migraines," but that dropped 40 percent on the drug, she said. "I have three kids, so for me it meant having more days when I was able to live my everyday life, cook a meal at home, go to events at school."

The second study tested fremanezumab (frem-uh-NEZZ-yoo-mab), from Teva Pharmaceutical, for chronic migraine, defined as headaches on 15 or more days per month, at least eight of them migraines.

About 1,000 patients were given monthly shots for three months: One third got the drug each time, another third got the drug the first time and then dummy shots the next two times, and the rest got dummy shots each time.

Monthly headache days dropped by four to five in the groups given the drug and by two to three for those given dummy treatments.

THE CAVEATS

Average reductions of one or two days a month are modest, but "there are some patients who have had a complete response - they become headache-free," Hershey said.

No worrisome side effects emerged, but the studies were very short, so long-term safety and effectiveness are unknown.

The new drugs were not tested against existing ones, only placebo treatments.

Many study leaders work for or have other financial ties to the drugmakers, and the companies helped analyze results.

Biotech drugs like these tend to be very expensive and if they're approved, insurers may set big copays or require patients to try older medicines first, Hershey said. When the drugs did work, the benefit was seen right away, so there's less financial risk in trying one or two doses.

"The patient will know quickly if this is a drug for them and if not, move on to something else," Hershey said.

Both drugs have been submitted to the U.S. Food and Drug Administration for approval. Eli Lilly and Co. and Alder Biopharmaceuticals also are testing similar drugs.

More information: Peter J. Goadsby et al. A Controlled Trial of Erenumab for Episodic Migraine, *New England Journal of Medicine* (2017). [DOI: 10.1056/NEJMoa1705848](https://doi.org/10.1056/NEJMoa1705848)

Stephen D. Silberstein et al, Fremanezumab for the Preventive Treatment of Chronic Migraine, *New England Journal of Medicine* (2017). [dx.doi.org/10.1056/NEJMoa1709038](https://doi.org/10.1056/NEJMoa1709038)

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