FULL-LENGTH ARTICLE NPub.org/xg6wge

Fremanezumab for preventive treatment of migraine

Functional status on headache-free days

Juliana VanderPluym, MD, David W. Dodick, MD, Richard B. Lipton, MD, et al.

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Correspondence
Dr. VanderPluym
VanderPluym.Juliana@mayo.edu

Study objective

To determine if fremanezumab improves functional performance on headache-free days (HFDs) for patients with migraine.

Summary results

Patients with migraine receiving fremanezumab had more HFDs with normal functional performance.

Classification of evidence

Class II.

What is known and what this paper adds

Migraine can impair functional performance during interictal periods. This study shows that patients receiving fremanezumab had more HFDs with normal functional performance.

Participants and setting

This study examined 297 patients with high-frequency episodic migraine (HFEM; i.e., 8–14 monthly headache days) and 263 patients with chronic migraine (CM; i.e., >15 monthly headache days) at 62 US sites between January 2014 and January 2015.

Design, size, and duration

This double-blind study assigned participants to treatment groups via central randomization. The participants with HFEM received placebo (n = 104) or fremanezumab at 225 mg/month (n = 96) or 675 mg/month (n = 97), and the participants with CM received placebo (n = 89) or fremanezumab at 675 mg (month 1) followed by 225 mg/month (n = 88) or 900 mg/month (n = 86). Participants used a daily electronic diary for 3 months. The functional outcomes included work/school/household chore performance, speed of work completion, concentration, and feeling of fatigue.

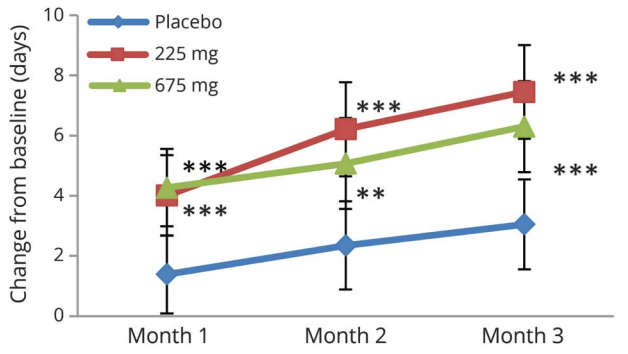
Primary outcome measures

The primary outcomes were the differences between the placebo- and fremanezumab-treated participants in functional performance on HFDs.

Main results and the role of chance

In the HFEM group, patients receiving fremanezumab consistently had more HFDs with normal functional performance in all measures ($p < 0.005$). In the CM group, patients on fremanezumab had increased HFDs with normal functional performance on some measures, such as freedom from concentration difficulties ($p \leq 0.0284$).

Figure Effect of fremanezumab on the number of HFDs



$^{**}p < 0.01$, $^{***}p < 0.001$.

Harms

No major drug-related adverse events were noted.

Bias, confounding, and other reasons for caution

Drug-related side effects might have unblinded some patients. This study did not use standardized questionnaires.

Generalizability to other populations

The lack of non-US sites may limit the generalizability of this study's results.

Study funding/potential competing interests

This study was funded by Teva. Some authors report receiving lecture honoraria, consulting fees, advisory board appointments or owning equity or serving on the boards of directors for healthcare companies; owning a patent; receiving editorial fees, travel/lecture fees, and royalty payments from various science publishers; and receiving grants from various foundations and the NIH. Go to Neurology.org/N for full disclosures.

Trial registration number

NCT02025556 and NCT02021773 on ClinicalTrials.gov.

A draft of the short-form article was written by M. Dalefield, a writer with Editage, a division of Cactus Communications. The authors of the full-length article and the journal editors edited and approved the final version.