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Long-term Efficacy and Safety of Erenumab

Results From 64 Weeks of the LIBERTY Study

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Study Question

Is erenumab a safe and effective long-term treatment for patients with treatment-resistant episodic migraine?

What Is Known and What This Paper Adds

Clinical trials with short follow-up show that erenumab is a safe and effective treatment for patients with episodic migraine who have not responded to other treatments. This investigation's results extend the observation period and provide further evidence for erenumab's safety and efficacy over 64 weeks of treatment.

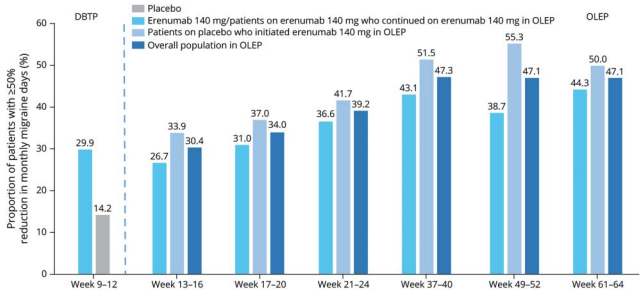
Methods

For these longitudinal analyses, the investigators analyzed data from 240 patients with episodic migraine that did not respond to 2–4 prior preventive treatments who had participated in the international LIBERTY study and completed the 12-week double-blind treatment phase (DBTP) and subsequently entered a 3-year open-label extension phase (OLEP), during which 118 patients continued taking erenumab (i.e., the "continuers") and 122 switched from placebo treatment to erenumab treatment (i.e., the "switchers"). Patients received erenumab through 140-mg subcutaneous injections performed every 4 weeks. The primary efficacy endpoint 52 weeks into the OLEP was a ≥50% reduction in monthly migraine days (MMDs) relative to the DBTP baseline. The present study's primary outcomes were longitudinal changes in 50% responder rates in the OLEP population overall and in the continuer and switcher subgroups.

Results and Study Limitations

Overall, 204 patients completed 52 weeks of the OLEP. In the general OLEP population, the 50% responder rate increased from weeks 13–16 until weeks 37–40 and then remained stable until weeks 61–64. For the continuers, the 50% responder rate increased from 29.9% in weeks 9–12 to 44.3% in weeks 61–64. For the switchers, the 50% responder rate was 50% in weeks 61–64. Adverse events occurred in ~80% of the OLEP participants. The current study provides Class IV evidence on data from patients with episodic migraine, that erenumab is safe and provides sustained efficacy at 52 weeks. A limitation of the present study is that patients with chronic migraine were not included and in the open label extension treatment was administered open-label to all the patients.

Figure Responder Rate, ≥50% Reduction in Monthly Migraine Days



Data were calculated as n/N (%); DBTP, double-blind treatment phase; n, number of responders; N, the total number of subjects in the treatment arm with response variable defined; OLEP, open-label extension phase.

Registration, Study Funding, and Competing Interests

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

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