

Erenumab in chronic migraine

Patient-reported outcomes in a randomized double-blind study

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Study objective and summary result

This study examined the effects of erenumab on health-related quality of life (HRQoL), headache burdens, and disability in patients with chronic migraine (CM), and it found that erenumab provides improvements in all 3 outcomes in patients with CM.

Classification of evidence

Class II.

What is known and what this paper adds

A randomized clinical trial showed that erenumab reduces monthly migraine days in patients with CM. This study further analyzed the trial's data to show that erenumab yields improvements in other outcomes.

Participants and setting

This trial included 667 adults with CM (83% female; mean age, 42 ± 11 years), which was defined as experiencing ≥15 headache days per month, including ≥8 migraine days. This trial was conducted through 69 sites in the US, Canada, and Europe, between March 2014 and April 2016.

Design, size, and duration

This double-blind phase 2 trial used a randomization scheme involving stratification by region and medication overuse to assign participants to groups receiving placebo treatment (n = 286) or erenumab at doses of 70-mg/mo (n = 191) or 140-mg/mo (n = 190). At baseline and follow-up timepoints, this trial assessed HRQoL, headache burdens, and migraine-related disability with the Migraine-Specific Quality-of-Life Questionnaire (MSQ), the Headache Impact Test (HIT-6), and the Migraine Disability Assessment Test (MIDAS), respectively.

Primary outcome measures

The primary outcomes were from-baseline changes in MSQ, HIT-6, and MIDAS scores at 3 months.

Main results and the role of chance

Greater-than-placebo improvements were observed for all 3 primary outcomes at both erenumab doses at 3 months.

Table Dose-specific outcomes at 3 months

Outcome	OR (95% CI) for outcome relative to placebo	
	70 mg/mo erenumab	140 mg/mo erenumab
MSQ-RFR score increase ≥5	1.9 (1.1–3.3)	2.8 (1.6–4.9)
HIT-6 total score decrease ≥5	2.3 (1.5–3.4)	2.3 (1.5–3.4)
MIDAS score consistent with severe disability	0.4 (0.3–0.7)	0.4 (0.2–0.6)

Abbreviations: CI = confidence interval; MSQ-RFR = role function-restrictive MSQ domain; OR = odds ratio. Score changes are relative to baseline.

Harms

Few participants experienced serious adverse events.

Bias, confounding, and other reasons for caution

This trial had a short duration.

Generalizability to other populations

This study's recruitment of participants in high-income countries may limit the generalizability of the results to residents of middle- and low-income countries.

Study funding/potential competing interests

This study was funded by Amgen. Some authors report receiving consulting and teaching fees, honoraria, committee appointments, and funding from the NIH and various healthcare companies, including Amgen; having stock and stock options in various healthcare companies, including Amgen; receiving publishing royalties; and receiving employment from Amgen and the American Headache Society. Go to Neurology.org/N for full disclosures.

Trial registration number

NCT02066415 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.

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