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Two randomized migraine studies of galcanezumab

Effects on patient functioning and disability

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Study objective and summary result

This study tested the hypothesis that galcanezumab, compared to placebo, improves daily functioning and ameliorates disability levels in patients with episodic migraine, and results confirmed the hypothesis.

Classification of evidence

Class II.

What is known and what this paper adds

Migraine is associated with disability and impaired functioning. This investigation shows that galcanezumab can address these aspects of migraine.

Participants and setting

This investigation used data from 1,773 adults with migraine (4–14 monthly headache days) who participated in either of 2 phase 3 clinical trials (EVOLVE-1 and EVOLVE-2) that were conducted through numerous centers in multiple countries.

Design, size, and duration

The participants were randomized 1:1:2 into groups receiving 240-mg/mo galcanezumab treatment (n = 435), 120-mg/mo galcanezumab treatment (n = 444), or placebo treatment (n = 894). After a 30–40-day baseline period, the participants entered a 6-month double-blind treatment period. The Migraine-Specific Quality of Life Questionnaire v2.1 (MSQv2.1) was used for monthly assessments of functioning, and the Migraine Disability Assessment (MIDAS) was used to assess disability levels in months 3 and 6.

Primary outcome measures

The primary outcomes were from-baseline changes in MSQv2.1 and MIDAS scores in months 4–6 and month 6, respectively.

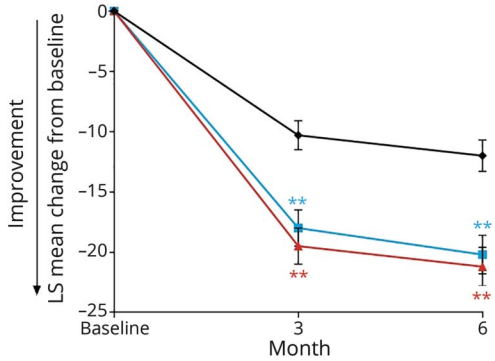
Main results and the role of chance

Galcanezumab treatment was associated with greater-than-placebo from-baseline improvements in MSQv2.1 scores and MIDAS scores ($p < 0.001$).

Harms

Adverse events were generally of mild-to-moderate severities.

Figure MIDAS score changes in EVOLVE-2 participants in the placebo (black), 120-mg/mo galcanezumab (red), and 240-mg/mo galcanezumab (blue) groups



LS = least squares. **$p < 0.001$ vs placebo.

Bias, confounding, and other reasons for caution

The baseline period was short.

Generalizability to other populations

The use of data from multiple countries favors the generalizability of the results.

Study funding/potential competing interests

This study was funded by Eli Lilly. Some authors report being current or former Eli Lilly employees and owning Eli Lilly stock; being employees and stockholders of other healthcare companies; receiving consulting fees, lecture honoraria, and committee appointments from the American Headache Society, the American Academy of Neurology, and various healthcare companies, including Eli Lilly; receiving funding from the NIH and various foundations; serving as advisors and editors for various journals, including *Neurology*®; and receiving publication royalties. Go to Neurology.org/N for full disclosures.

Trial registration number

NCT02614183 (EVOLVE-1) and NCT02614196 (EVOLVE-2) on ClinicalTrials.gov.

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