

Efficacy and safety of 2 dose regimens of subcutaneous administration of fremanezumab versus placebo for the preventive treatment of episodic migraine

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Evaluate two subcutaneous dose regimens of fremanezumab for the preventive treatment of episodic migraine (EM). 16-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group adult EM study. Daily diaries maintained during 28-day baseline period. Patient assigned to 1 of 3 treatment groups: (1)monthly: 225 mg fremanezumab at months 1, 2 and 3, (2)quarterly: 675 mg fremanezumab at month 1, followed by placebo injections at months 2 and 3, and (3)monthly administration of matching placebo. Primary efficacy endpoint, mean change from baseline to 12-week randomization period in monthly average number of migraine days was analyzed using an analysis of covariance method or the Wilcoxon rank sum test. The mean number of migraine days was 9.1 days during the 28-day baseline period. Fremanezumab- treated patients had significant reductions in the number of monthly migraine days during the 12-week period vs. placebo (-2.2 days from baseline=9.1 days), for both regimens[monthly -3.7 days from baseline=9.2 days; quarterly(-3.4 days from baseline=8.9 days); p0.0001], and 4-weeks after 1st dose, for both regimens (p0.0001). Fremanezumab-treated patients had significant reductions in the number of monthly headache days of at least moderate severity [monthly (-2.9 days); quarterly(-3.0 days); vs placebo(-1.5 days); p0.0001], and 4-weeks after 1st dose, for both regimens (p0.0001). Fremanezumab treatment resulted in statistically significant reductions in the number of monthly days of acute headache medication use [monthly(-3.0 days); quarterly(-2.9 days); p0.0001] versus placebo (-1.6 days). Most common adverse events were injection site reactions. These results confirm the efficacy, safety, tolerability, and flexible dosing profile of fremanezumab for the preventive treatment of episodic migraine.