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Articles

Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial

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Summary

Background

The calcitonin gene-related peptide (CGRP) pathway is important in migraine pathophysiology. We assessed the efficacy and safety of erenumab, a fully human monoclonal antibody against the CGRP receptor, in patients with chronic migraine.

Methods

This was a phase 2, randomised, double-blind, placebo-controlled, multicentre study of erenumab for adults aged 18–65 years with chronic migraine, enrolled from 69 headache and clinical research centres
more headache days per
randomly assigned (3:2:2
given every 4 weeks for
voice or web response s
masked to treatment ass
days from baseline to the last 4 weeks of double-blind treatment (weeks 9–12). Safety endpoints were adverse events, clinical laboratory values, vital signs, and anti-erenumab antibodies. The efficacy analysis set included patients who received at least one dose of investigational product and completed at least one post-baseline monthly measurement. The safety analysis set included patients who received at least one dose of investigational product. The study is registered with ClinicalTrials.gov, number NCT02066415.

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Findings

From April 3, 2014, to Dec 4, 2015, 667 patients were randomly assigned to receive placebo (n=286), erenumab 70 mg (n=191), or erenumab 140 mg (n=190). Erenumab 70 mg and 140 mg reduced monthly migraine days versus placebo (both doses −6·6 days *vs* placebo −4·2 days; difference −2·5, 95% CI −3·5 to −1·4, p<0·0001). Adverse events were reported in 110 (39%) of 282 patients, 83 (44%) of 190 patients, and 88 (47%) of 188 patients in the placebo, 70 mg, and 140 mg groups, respectively. The most frequent adverse events were injection-site pain, upper respiratory tract infection, and nausea. Serious adverse events were reported by seven (2%), six (3%), and two (1%) patients, respectively; none were reported in more than one patient in any group or led to discontinuation. 11 patients in the 70 mg group and three in the 140 mg group had anti-erenumab binding antibodies; none had anti-erenumab neutralising antibodies. No clinically significant abnormalities in vital signs, laboratory results, or electrocardiogram findings were identified. Of 667 patients randomly assigned to treatment, 637 completed treatment. Four withdrew because of adverse events, two each in the placebo and 140 mg groups.

Interpretation

In patients with chronic migraine, erenumab 70 mg and 140 mg reduced the number of monthly migraine days with a safety profile similar to placebo, providing evidence that erenumab could be a potential therapy for migraine prevention. Further research is needed to understand long-term efficacy and safety of erenumab, and the applicability of this study to real-world settings.

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Amgen.