

REAL-WORLD EFFECTIVENESS AND SAFETY OF RIMEGEPANT AS PREVENTIVE TREATMENT FOR EPISODIC MIGRAINE: STUDY PROTOCOL OF AN ONGOING PROSPECTIVE SINGLE-CENTER OBSERVATIONAL STUDY

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Background. A significant proportion of patients with episodic migraine either do not receive appropriate prophylaxis or discontinue treatment early due to insufficient efficacy or adverse events [1]. This study aims to evaluate the real-world effectiveness and safety of Rimegepant as a preventive treatment in adult patients with episodic migraine.

Methods. This prospective, observational study is conducted in a tertiary headache center, including adult patients with migraine with or without aura according to the International Classification of Headache Disorders, 3rd edition criteria, presenting an indication for preventive treatment, and with documented failure, intolerance, or contraindication to at least three classes of conventional preventive therapies. Patients receive rimegepant 75 mg every other day. Follow-up visits are performed every 3 months for 12 months using headache diaries and validated patient-reported outcome questionnaires, including Headache Impact Test-6 items (HIT-6), Migraine Disability Assessment (MIDAS) and Migraine-Specific Quality of Life Questionnaire (MSQ). The primary endpoint is the change in MMD at 3 months compared with baseline. Secondary endpoints include ≥50% responder rates, changes in monthly headache days, acute medication use, headache-related disability, quality of life, and safety outcomes.

Results. The study is currently ongoing. Preliminary data from the first patients who completed the 3-month follow-up showed a reduction in MMD. At baseline, the median number of MMD was 7, decreasing to 4 at 3 months, corresponding to a median reduction of 3 days ($p = 0.031$). No serious adverse events or discontinuations due to tolerability were recorded in this preliminary cohort.

Conclusions. Preliminary real-world data suggest that rimegepant may represent an effective and well-tolerated preventive treatment option for patients with episodic migraine and multiple prior preventive treatment failures. Early findings indicate a clinically meaningful reduction in monthly migraine days at 3 months, with a favorable safety profile. Although limited by the small sample size and the ongoing nature of the study, these results provide encouraging early evidence and warrant further evaluation in the full study cohort.