NOVARTIS

CAMG334AAE02 Study Results Abstract for Public Disclosure

Title

Real-world experience of patients newly started on Erenumab in the UAE: A Longitudinal prospective observational study (terminated early)

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Migraine, erenumab, United Arab Emirates, real-world evidence, early termination

Rationale and background

Migraine is a prevalent and disabling neurological disorder affecting over 10% of the world's population, with higher prevalence in females. It is categorized into Episodic Migraine (EM) and Chronic Migraine (CM) based on headache frequency. Erenumab, a CGRP receptor antagonist, has been approved for migraine prevention in adults. While clinical trials typically assess changes in monthly migraine days and acute medication use, there was growing interest in patient-centric outcomes such as treatment satisfaction and quality of life. This study aimed to address the lack of local reporting on patient experiences with erenumab in the UAE, focusing on patient-reported outcomes and treatment-related satisfaction. Understanding these factors was crucial as treatment satisfaction is closely correlated with medication adherence and efficacy in reducing migraine burden.

Research question and objectives

The primary objective was to evaluate the effect of erenumab on medication-specific treatment satisfaction in patients newly started on erenumab over 12 weeks using the TSQM. Secondary objectives included assessing changes from baseline to week 12 in: disease severity (HIT-6), disease burden (MIDAS), work-related burden (WPAI), patients' global impression of change (PGIC), and migraine symptoms (MMDs, MSMDs, MHDs). The study also aimed to describe baseline characteristics of migraine patients starting erenumab and to report on TSQM domains of side effects, convenience, and effectiveness. However, due to the study's early termination, these objectives could not be fully addressed, and only baseline data were collected.

Study design

This was intended to be a longitudinal prospective descriptive study using a 20-minute online survey, planned for multiple Gulf countries over 6 months with a 12-week follow-up. Patients were selected by neurologists/headache specialists in clinics and hospitals. The survey included a 5-minute screener and the main questionnaire. However, due to recruitment challenges, only the baseline wave in the UAE was completed before early termination. Data collection lasted 167 days (5-Jun-2024 to 18-Nov-2024), exceeding the planned 6-month period. The 12-week follow-up was not conducted.

Setting

The study was conducted in clinics and hospitals treating adult migraine patients in the UAE. Originally planned to include Qatar, Oman, and Kuwait, recruitment challenges limited participation to UAE sites only. Data collection occurred over 167 days (approximately 5.5 months), from 5-Jun-2024 to 18-Nov-2024, extending beyond the initially planned 6-month period. An online survey was used to collect baseline data immediately upon recruitment. The planned 12-week follow-up data collection did not occur due to early study termination.

Subjects and study size, including dropouts

The study aimed to recruit 200 adult migraine patients newly started on erenumab (70 mg or 140 mg) across four Gulf countries (UAE, Kuwait, Oman, Qatar). Eligibility criteria included age >18 years, episodic or chronic migraine (with or without medication overuse headache), and ability to receive 3 monthly doses of erenumab. The planned sample size was calculated to provide a margin of error of 6.8% with a 95% confidence level. However, due to recruitment challenges and early termination, only 37 patients from the UAE were enrolled. This significant reduction in sample size and limitation to a single country impact the precision and generalizability of the results. The planned 12-week follow-up was not conducted, and only baseline data were collected.

Variables and data sources

Data were collected via a single online survey at baseline, consisting of a 5-minute screener and a 20-minute questionnaire. Variables included demographics, migraine characteristics, and validated questionnaires (HIT-6, WPAI, MIDAS). Additional measures included Monthly Migraine Days (MMDs), Monthly Headache Days (MHDs), and Monthly Severe Migraine Days (MSMDs). The survey, developed by Ipsos and Novartis, combined validated tools with non-validated questions tailored to study objectives. All data were self-reported and anonymized. While originally planned, TSQM and PGIC questionnaires and 12-week follow-up data were not collected due to early study termination.

Statistical methods

Due to early termination and collection of only baseline data, analyses were purely descriptive. Ipsos performed all analyses using SPSS and Dimensions. Categorical data were reported as numbers and percentages, while continuous data were presented as mean (SD) or median (IQR) as appropriate. No hypothesis testing, sensitivity analyses, or data imputation were conducted. Planned analyses, including follow-up comparisons, subgroup analyses, and correlation analyses, could not be performed due to lack of follow-up data and limited sample size. Results should be interpreted cautiously given these significant limitations.

Results

The study enrolled 37 participants from the UAE, predominantly female (84%) with a mean age of 25.6 years. Key findings include:

1. Significant migraine-related disability: HIT-6 results showed substantial impact on daily life, with 'feeling fed up or irritated' and 'limiting concentration' being the most affected areas (both mean scores 4.0/5).
2. High disease burden: MIDAS results revealed an average of 15.1 days of missed household work and 13 days of reduced work/school productivity over three months.
3. Work productivity impact: WPAI results showed an average of 8.3 hours missed due to migraines in the past week, with high impact on work productivity (mean score 7.0/10) and daily activities (7.6/10).
4. Migraine frequency: Participants experienced a median of 8-10 migraine days and 12 headache days per month.
5. Symptom profile: Most common symptoms were sensitivity to light (97%), severe 'throbbing' pain (86%), and sensitivity to sound (84%).
6. Treatment history: Median of 2 failed preventative treatments before initiating erenumab. Pain relievers were the most common current acute therapy (62%).
7. Safety: 37 adverse events were reported, consistent with erenumab's known safety profile.

These baseline data provide insights into the characteristics and disease burden of migraine patients initiating erenumab in the UAE. However, it's important to note that due to the small sample size (n=37) and the study's premature termination, these results should be interpreted with caution. They provide a

snapshot of the study population at baseline but do not reflect any changes over time or treatment effects as originally planned.

Discussion

While the study's early termination limited its ability to meet original objectives, baseline data provided valuable insights into characteristics of migraine patients initiating erenumab in the UAE. The predominantly female (84%), young (mean age 25.6 years) population reported significant migraine-related disability and high disease burden, aligning with global trends. The median of 8-10 migraine days and 12 headache days per month, along with substantial impact on work productivity, underscore the severity of migraine in this population. A notable delay between first symptoms, diagnosis, and preventive treatment initiation suggests potential areas for improvement in migraine management pathways. However, the study's limitations - including early termination, small sample size (n=37), single-country focus, and reliance on self-reported data - significantly restrict the generalizability of these findings. The high proportion of Emirati nationals (70%) may reflect specific cultural and healthcare access patterns. Despite these limitations, this study provides a foundation for understanding erenumab use in real-world settings in the UAE and highlights the need for larger, longer-term studies in the region.

Conclusion

Despite early termination, this study provides valuable baseline data on migraine patients in the UAE, highlighting the need for effective management strategies and further research in this population.

Despite early termination preventing assessment of erenumab's effects over time, this study provides valuable baseline insights into migraine patients initiating erenumab treatment in the UAE. Key findings include a predominantly female (84%) and young (mean age 25.6 years) population, significant migraine-related disability, high disease burden (median 8-10 migraine days/month), and notable delays in preventive treatment initiation. While the study's limitations – early termination, small sample size (n=37), and single-country focus – restrict result generalizability, it represents an important first step in understanding real-world erenumab use in the UAE. The baseline data collected provides a foundation for future research and may inform clinical practice in migraine management in the UAE and potentially the broader Gulf region. Larger, longer-term studies are needed to better understand migraine characteristics, treatment patterns, and CGRP antagonist effectiveness in real-world settings in this region.

1 List of abbreviations

CM	Chronic Migraine
EM	Episodic Migraine
HIT-6	Headache Impact Test-6
MHD	Migraine Headache Days
MIDAS	Migraine Disability Assessment
MMD	Monthly Migraine Days
MSMD	Migraine Specific Medication Days
NIS	Non-Interventional Study
PGIC	Patients' Global Impression of Change
TSQM	Treatment Satisfaction Questionnaire for Medication
WPAI	Work Productivity and Activity Impairment