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What is the consistency of response to rimegepant at a group level in the acute treatment of migraine in UK adult patients? Protocol for a real-world, patient-centred study

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OBJECTIVES

- Rimegepant is a small-molecule calcitonin gene-related peptide (CGRP) antagonist licensed for the acute treatment of migraine and prevention of episodic migraine in adults.
- Efficacy and tolerability have been demonstrated in clinical trials[1,2].
- Real-world effectiveness across multiple attacks over four weeks has been assessed in the US CONFIDENCE study (NCT06467370)[3].
- CORRELATE-UK (NCT06898047) is a real-world study to evaluate the effectiveness of rimegepant for the acute treatment of migraine across multiple attacks in a UK population.
- The primary objective is to evaluate group-level consistency of response to rimegepant across multiple attacks over 12 weeks, as assessed by meaningful pain relief (MPR).
- Key secondary objectives are as follows:
  1. to determine the group-level consistency of response to rimegepant for meaningful improvement in migraine-related non-pain symptoms.
  2. to determine the proportion of participants optimised on an acute migraine treatment regimen that includes rimegepant over 12 weeks.

METHODS

STUDY DESIGN

- This is a prospective observational, non-interventional, real-world cohort study involving 9 UK healthcare institutions (see **Figure 1**) .
- **Figure 2** presents an overview of the study design.
- Participants will be identified by the participating healthcare institutions and directed to enrol via the Vitaccess Real™ digital platform, where they will complete eligibility screening and provide electronic informed consent via smartphone or other connected device.
- A total of 250 participants will be enrolled, with an approximately 50:50 ratio of episodic migraine and chronic migraine, monitored through ongoing review during recruitment.

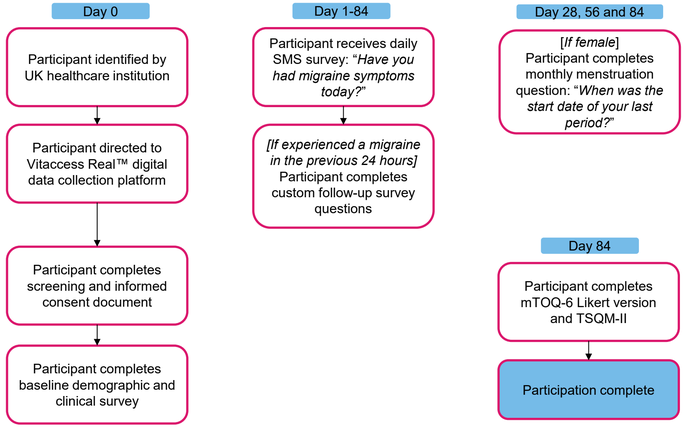
STUDY POPULATION

- UK adults with migraine, including those newly prescribed rimegepant for acute treatment.
- Must have experienced at least four migraine attacks in the 28 days prior to study enrolment.
- Stable use of migraine preventives (other than rimegepant) is permitted: oral, monthly injectable (most recent dose within 3 weeks), or quarterly injectable (most recent dose within 2 months).

Figure 1. Site distribution

Locations represented: Cumbria, Hull, Leeds, Liverpool, London (4 sites), and Oxford.

Figure 2. Study flowchart



mTOQ-6=Migraine Treatment Optimization Questionnaire; TSQM-II=Treatment Satisfaction Questionnaire for Medication II

PARTICIPANT ACTIVITIES

- Following registration, participants will complete a baseline demographic and clinical survey within 72 hours via data capture platform.
- For 12 weeks, participants will receive a daily single-item SMS survey asking whether they have experienced migraine symptoms in the past 24 hours (**Figure 3**).
- If participants reply in the affirmative, they will receive an SMS with a link to the platform to complete the digital diary, which captures rimegepant use, time to MPR (**Figure 3**) and restoration of function, and treatment satisfaction. They will have a 96-hour window in which to complete these questions.
- Female participants will be asked to complete a monthly menstruation question via the platform.
- At study end (Day 84), participants will use the platform to complete the 6-item Migraine Treatment Optimization Questionnaire (mTOQ-6; Likert scale version) and the Treatment Satisfaction Questionnaire for Medication II (TSQM-II).
  - The mTOQ-6 is a validated 6-item questionnaire designed to assess response to acute treatment in people living with migraine. It evaluates the respondent's perception of their acute treatment regimen by assessing efficacy at two and 24 hours, tolerability, ability to plan daily activities, feeling of being in control, and ability to return to normal activities[4].
  - The TSQM-II is a generic patient-reported measure developed to assess patients' satisfaction with medication[5]. It is validated for migraine and includes 11 items covering four satisfaction domains: effectiveness, side effects, convenience of use and overall satisfaction with treatment.

OUTCOMES

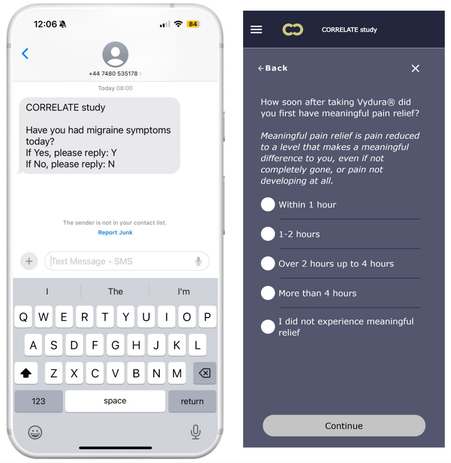
1. Time to MPR or meaningful functional improvement (<1, >1-2, >2-4, or >4h, or no relief/improvement)
   - Defined as time after rimegepant intake when participants experienced reduced pain or improved function that they considered meaningful
2. Treatment satisfaction with rimegepant across different domains (pain reduction, attack duration, speed of action, cognitive symptoms, and overall)
   - Measured using a 7-point rating scale ranging from extremely satisfied to extremely dissatisfied

ANALYSIS

- Group-level consistency
  - Proportion of all rimegepant-treated attacks achieving MPR and meaningful functional improvement within 2 h post dose.
- Secondary objectives
  - Proportion of attacks with meaningful improvement in non-pain symptoms at 2 h
  - Proportion of participants on an acute migraine regimen including rimegepant over the 12-week follow up period

All data will be summarized using descriptive statistics, and no hypothesis testing will be performed.

Figure 3. Daily SMS survey and survey question assessing MPR



PARTICIPANT ENGAGEMENT

- Following consultation with people who experience migraines, the platform has a migraine-friendly, dark, muted colour scheme to reduce visual strain and improve usability for users sensitive to bright or high-contrast displays.
- To encourage survey completion, participants will be sent SMS and/or email reminders.
- All surveys have a 96-hour completion window, to allow participants to complete data entry at a time of their choosing, when they are feeling well. Participants can save incomplete surveys and return at a later time within the completion window.
- Participants will be compensated with shopping vouchers for survey completions.

RESULTS

- Recruitment began November 2025. Results will be shared once available.
- An interim analysis is planned for approximately four months from the start of data collection. The planned interim analysis will review data from participants who have provided at least four weeks of daily surveys at the point of the interim analysis.
- Final results are expected by the end of 2026.

CONCLUSIONS

- CORRELATE-UK will assess the real-world effectiveness of rimegepant for acute migraine treatment across multiple attacks over 12 weeks in a UK population, including participants newly initiated on rimegepant, and those with chronic migraine.
- Longitudinal data capture will allow the determination of treatment effectiveness across multiple attacks, while the observational design will ensure the data reflect a real-world setting.
- A patient-centred real-time approach will allow for the capture of granular data and will minimise patient recall bias, which is important for subjective outcomes such as pain.
- Demonstrating group-level consistency of response to rimegepant will provide decision makers, clinicians and patients with greater confidence in using rimegepant for multiple attacks.

REFERENCES

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CONFLICTS OF INTEREST

GO, LA, RP, KN: employed by and holds stock/options in Pfizer. EB, AF, SL: employees of Vitaccess, which was commissioned by Pfizer to run this study and prepare this poster. GL: received consulting fees from Pfizer.

ACKNOWLEDGEMENTS

Juan Fernandez, Sophie Kilpatrick, Marius Munteanu, and Ciara Ringland participated in Vitaccess Real™ digital platform user acceptance testing and their feedback shaped the final study platform. Karina Kauffmann, Marius Munteanu and Rowena Randall made substantial contributions to the study protocol.

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Presented at the 19th European Headache Congress, December 3-6, 2025, Lisbon, Portugal