

# Randomized Study in Children and Adolescents With Migraine: Acute Treatment

NCT04649242

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Status	RECRUITING
Phase	Phase 3
Sponsor	Pfizer
Enrollment	2,100 participants

## Key Eligibility Criteria

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### Inclusion (10)

- History of migraine (with or without aura) for  $\geq$  6 months before Screening according to the IHS Classification ICHD-319 specifications for pediatric migraine. History may be verified using both medical records and recall by the participant and/or participant's parent(s)/legal representative(s).
- History of 1 to 8 moderate or severe attacks per month during the 2 months prior to enrollment, with attacks lasting  $\geq$  3 hours without treatment, and attacks occurring at intervals  $\geq$  24 hours.
- Prophylactic migraine medication are permitted if the dose has been stable for at least 12 weeks prior to the Baseline Visit, and the dose is not expected to change during the course of the study.
- Participants may remain on one (1) medication with possible migraine prophylactic effects, excluding CGRP antagonists [biologic or small molecule], during the treatment phases.
- Concomitant use of a CGRP antagonist, such as erenumab or fremanezumab, is prohibited.

... and 5 more (see full listing online)

### Exclusion (10)

- History of cluster headache or hemiplegic migraine headache.
- Confounding and clinically significant pain syndrome that may interfere with the participant's ability to participate in this study.
- Current psychiatric condition that is uncontrolled and/or untreated for a minimum of 6 months prior to the Screening Visit. Participants with a lifetime history of psychosis and/or mania.
- History of suicidal behavior or major psychiatric disorder.
- Current diagnosis or history of substance abuse; positive drug test at Screening.

... and 5 more (see full listing online)

## Locations (245 total)

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Achieve Clinical Research, LLC d/b/a Accel Research Sites-Neurology and Neurodiagnostic of Alabama, Birmingham, Alabama, United States

Perseverance Research Center, LLC, Scottsdale, Arizona, United States

Physicians Research Group, Tempe, Arizona, United States

... and 242 more locations

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<https://clinicaltrials.gov/study/NCT04649242>

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