

Qudexy XR for the Prevention of Migraine in Children 6 to 11 Years Old

NCT04748601

Status	RECRUITING
Phase	Phase 4
Sponsor	Upsher-Smith Laboratories
Enrollment	132 participants

Key Eligibility Criteria

Inclusion (5)

- Subject is a female or male 6 to 11 years of age, inclusive, at Visit 1 (Screening)
- Subject weighs at least 17.0 kg and less than 50.0 kg at Visit 1 (Screening) based on 95 percentile weight for the age range.11
- Subject has at least a 6-month history of headaches consistent with a diagnosis of migraine with or without aura (International Classification of Headache Disorders, 3rd Edition \[ICHD 3\]).
- Subject had e8 self-reported headache days in the 28 days prior to Screening.
- Subject has a PedMIDAS score ≥ 10 , indicating at least mild disruption in daily activities, and ≤ 140 , indicating extreme disability that may require more comprehensive, multi component therapy.

Exclusion (12)

- Subject has continuous migraines, defined as an unrelenting headache for a 28-day period.
- Subject is currently receiving treatment or has used Botulinum toxin (Botox®) within 3 months prior to Visit 1 (Screening).
- Subject is currently receiving migraine prevention medication and has initiated or changed the dose within 28 days of Screening or is unwilling to avoid making a change during the duration of the study.
- Subject has previously failed an adequate trial of topiramate (at least 3 months duration at a clinically appropriate dose) for prophylaxis of migraine headache due to lack of efficacy or AEs.
- Subject has previously failed an adequate trial of ≥ 3 migraine preventative medications.

... and 7 more (see full listing online)

Locations (15 total)

Upsher-Smith Clinical Trial Site #5, Birmingham, Alabama, United States
Upsher-Smith Clinical Trial Site #15, La Jolla, California, United States
Upsher-Smith Clinical Trials Site #3, Aurora, Colorado, United States
... and 12 more locations