

A Study of Eptinezumab in Pediatric Participants With Episodic Migraine

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 6 years to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Diagnosis of migraine (with or without aura) according to the International Classification of Headache Disorders, 3rd edition (ICHD-3; in the opinion of the investigator) with history of migraine headaches of at least 6 months prior to the Screening Visit.
- During the 28-day screening period, the participant (and their parent/caregiver, when applicable) must adequately complete the headache eDiary (≥ 23 of the 28 days) following the day of the Screening Visit.
- During the 28-day screening period, the participant must have ≤ 14 headache days, of which at least 4 are migraine days as documented in the eDiary.

Exclusion Criteria:

- History or diagnosis of chronic tension-type headache, hypnic headache, cluster headache, hemicrania continua, new daily persistent headache, or unusual migraine subtypes (previously referred to as complicated migraine), such as hemiplegic migraine (sporadic and familial), migraine with brainstem aura, recurrent painful ophthalmic neuropathy, or migraine with neurological accompaniments that are not typical of migraine aura (diplopia, altered consciousness, or long duration, e.g., >60 min).
- History of moderate or severe head trauma or other neurological disorder or systemic medical disease that is, in the investigator's opinion, likely to affect the functions of the central nervous system.
- 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 are excluded.
- Any other disorder for which the treatment takes priority over treatment of migraine or is likely to interfere with study treatment or impair treatment compliance.

Other inclusion and exclusion criteria may apply.

Conditions & Interventions

Interventions:

DRUG: Eptinezumab, DRUG: Placebo

Conditions:

Episodic Migraine

More Information

Description:

The main goal of this trial is to learn whether eptinezumab helps reduce the number of days with episodic migraine in pediatric participants.

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Principal Investigator:

Principal Investigator ID:

Phase: PHASE3

IRB Number:

System ID: NCT05897320

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