

Evaluating the Pharmacokinetics, Pharmacodynamics, and Safety of Efgartigimod Administered Intravenously in Children With Generalized Myasthenia Gravis

NCT04833894

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	argenx
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (9)

- Ability of the participant and/or his/her legally authorized representative to understand the requirements of the trial and provide written informed consent/assent, if applicable (including consent/assent for the use and disclosure of research-related health information), willingness and ability to comply with the trial protocol procedures (including attending the required trial visits).
 - Male or female participants between 2 to less than 18 years of age at the time of providing informed consent/assent. Age groups are enrolled in a staggered fashion respectively: 6 participants in the 12 to less than 18 years of age group followed by 6 participants in the 2 to less than 12 years of age group at the time of providing informed consent/assent.
 - Diagnosed with Generalized Myasthenia Gravis (gMG) with confirmed documentation
 - Meeting the clinical criteria as defined by the Myasthenia Gravis Foundation of America (MGFA) class II, III, and IVa.
 - Eligible participants should have an unsatisfactory response (efficacy and/or safety) to immunosuppressants, steroids or acetylcholinesterase (AChE) inhibitors and should be on stable concomitant gMG therapy of adequate duration before screening.
- ... and 4 more (see full listing online)

Exclusion (18)

- Participants with MGFA class I, IVb, and V.
- Female adolescents of childbearing potential: Pregnancy or lactation, or the participant intends to become pregnant during the trial or within 90 days after the last dose of IMP.
- Has any of the following medical conditions:
- Clinically significant uncontrolled active or chronic bacterial, viral, or fungal infection at screening.
- Any other known autoimmune disease that, in the opinion of the investigator, would interfere with an accurate assessment of clinical symptoms of myasthenia gravis or put the participant at undue risk.

... and 13 more (see full listing online)

Locations (25 total)

Ann and Robert H Lurie Children's Hospital of Chicago - Main Hospital, Chicago, Illinois, United States
University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, United States
University of Virginia (UVA) Health - Developmental Pediatrics Clinic, Charlottesville, Virginia, United States
... and 22 more locations