

A Study of Rozanolixizumab in Pediatric Study Participants With Moderate to Severe Generalized Myasthenia Gravis

NCT06149559

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	UCB Biopharma SRL
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (5)

- Study participant must be ≥2 to <18 years of age inclusive, at the time of signing the informed consent/assent according to local regulation
- Study participant must have a documented diagnosis of generalized Myasthenia Gravis (gMG) at Screening that includes a record confirming the presence of MG specific autoantibodies to acetylcholine receptor (AChR) or muscle-specific kinase (MuSK) prior to Screening
- Study participant has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification II to IVa at Screening
- Study participant has received existing conventional treatment(s) for gMG (eg, pyridostigmine, corticosteroids, and/or immune suppressants) prior to Screening
- Study participant has had an unsatisfactory clinical response or worsening of gMG symptoms and is in need of additional therapy (for example, plasma exchange (PEX) or treatment with intravenous immunoglobulin (IVIg))

Exclusion (6)

- Study participant with severe weakness affecting oropharyngeal or respiratory muscles, or who has myasthenic crisis or impending crisis at Screening or Baseline
- Study participant has a known hypersensitivity to any components of the Investigational Medicinal Product (IMP) or other anti-neonatal-Fc receptor (FcRn) medications
- Study participant with any active or untreated thymoma
- Study participant has a history of thymectomy within 6 months prior to Screening
- Study participant has a clinically relevant active infection (eg, sepsis, pneumonia, or abscess) in the opinion of the Investigator, or had a serious infection (resulting in hospitalization or requiring parenteral antibiotic treatment) within 6 weeks prior to the first dose of IMP

... and 1 more (see full listing online)

Locations (13 total)

Mg0006 50574, Flower Mound, Texas, United States
Mg0006 40290, Bologna, Italy
Mg0006 40144, Milan, Italy
... and 10 more locations