A Study to Investigate the Efficacy, Safety and Tolerability of Remibrutinib Versus Placebo in Adult Patients With Generalized Myasthenia Gravis

NCT06744920

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	180 participants

Key Eligibility Criteria

Inclusion (6)

- Adult patients with gMG (age 18-75 years)
- Confirmed diagnosis of Myasthenia Gravis Foundation of America (MGFA) Class II-IV gMG at screening and likely not in need of a respirator for the duration of the study, as judged by the Investigator
- Documented evidence of positive serologic testing for AChR+ antibody or MuSK+ antibody at screening, OR seronegative for both AChR and MuSK antibodies at screening
- Baseline MG-ADL score e 6 with e 50% of the total score due to non ocular symptoms
- Participants who have been on a stable dose of standard-of-care treatment as specified in the protocol

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

Exclusion (2)

- Prior to baseline have been treated with intravenous immunoglobulins or plasma exchange (IVIg/PLEX) in the past month, with rituximab in the past 6 months, eculizumab in the past 2 months, ravulizumab or other complement inhibitors in the past 3 months, efgartigimod or other anti-FcRn therapies in the past 3 months, or had a thymectomy in the past 6 months or a planned thymectomy during the trial period
- Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 1 week after stopping of study treatment

Locations (93 total)

Neuromuscular Research Center, Phoenix, Arizona, United States
Honor Health Research Institute, Scottsdale, Arizona, United States
Fullerton Neuro and Headache Ctr, Fullerton, California, United States
... and 90 more locations