

A Phase III Study to Investigate Efficacy, Safety and Tolerability of Iptacopan Compared With Placebo in Participants Aged 18 to 85 Years With gMG.

NCT06517758

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	146 participants

Key Eligibility Criteria

Inclusion (16)

- Adult patients with generalized Myasthenia Gravis (age 18-85 years) at screening
 - Positive serology testing for AChR+ antibody at screening
 - 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.
 - The confirmation of the diagnosis of gMG should be documented and supported by e1 of the following 3 tests:
 - History of abnormal neuromuscular transmission demonstrated by single-fiber electromyography or repetitive nerve stimulation.
- ... and 11 more (see full listing online)

Exclusion (9)

- Have been treated with intravenous immunoglobulin (IVIG)/plasma exchange (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.
 - Participants with clinically significant active or chronic uncontrolled bacterial, viral, or fungal infection at screening, including patients who test positive for an active viral infection at screening with: Active Hepatitis B Virus (HBV); Active Hepatitis C Virus (HCV);
 - Human Immunodeficiency Virus (HIV) positive serology associated with an Acquired Immune Deficiency Syndrome (AIDS)-defining condition or with a cluster of differentiation 4 (CD4) count
 - cells/mm³
 - Female participants who are pregnant or lactating, or are intending to become pregnant.
- ... and 4 more (see full listing online)

Locations (110 total)

Honor Health Research Institute, Scottsdale, Arizona, United States
Fullerton Neuro and Headache Ctr, Fullerton, California, United States
SC3 Research Pasadena, Pasadena, California, United States
... and 107 more locations

<https://clinicaltrials.gov/study/NCT06517758>

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