Seronegative Myasthenia Gravis - Efgartigimod IV

NCT06587867

Status	RECRUITING
Phase	Phase 3
Sponsor	University Health Network, Toronto
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (13)

• Evidence of signed and dated informed consent document(s) indicating that the subject has been informed of all pertinent aspects of the trial. Subjects must be willing and able to comply with the protocol, complete study assessments, and return for follow-up visits.

• Male or female subjects e 18 years old.

• Diagnosis of SN MG defined as: (a) clinical syndrome consistent with a diagnosis of MG, and not otherwise explained by another condition, (b) abnormal neuromuscular transmission test results demonstrated by single-fiber electromyography or repetitive nerve stimulation; and (c) negative serologic test for anti-AChR and anti- MuSK antibodies as confirmed at screening, (d) limited, if any, response to therapy with immunotherapy and/or antiacetylcholinesterase (AChE) treatment. Further testing for low affinity antibodies to rapsyn-clustered AChR by cell-based assays will be done at baseline and the results included as part of subgroup analysis. All patients will have a negative genetic test for congenital myasthenic syndromes by history or at baseline to exclude the possibility of congenital myasthenic syndrome mimicking SN MG.

• MGFA Clinical Classification Class II, III, or IV at the time of screening and baseline.

• Moderate to severe myasthenia gravis as defined by a generalized myasthenia gravis impairment index score \> 11 or MG-ADL score of at least 5 (with \>50% of the score due to non-ocular symptoms) and a PASS response of "No" and a SSQ of \< 70% with at least 6 months of historical data as the baseline.

... and 8 more (see full listing online)

Exclusion (13)

• Patients who discontinued early from trials of efgartigimod for pregnancy or rescue reasons or an SAE that was likely to result in a life-threatening situation or pose a serious safety risk.

• Pregnant and lactating women, and those intending to become pregnant during the trial or within 3 months after the last dosing. Women of childbearing potential should have a negative urine pregnancy test at screening and baseline.

• Male patients who are sexually active and do not intend to use effective methods of contraception (as mentioned above) during the trial or within 3 months after the last dosing or male patients who plan to donate sperm during the trial or within 3 months after the last dosing.

• Patients with known hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV) seropositivity.

• Patients with known autoimmune disease other than MG (e.g., rheumatoid arthritis) which in the investigator opinion would interfere with an accurate assessment of clinical symptoms.

... and 8 more (see full listing online)

Locations (1 total)

University Health Network, Division of Neurology, Toronto General Hospital, Toronto, Ontario, Canada