Efficacy and Safety of a New Formulation of Oral Cladribine Compared With Placebo in Participants With Generalized Myasthenia Gravis (MyClad)

NCT06463587

Status	RECRUITING
Phase	Phase 3
Sponsor	Merck Healthcare KGaA, Darmstadt, Germany, an affiliate of Merck KGaA, Darmstadt, Germany
Enrollment	264 participants

Key Eligibility Criteria

Inclusion (8)

- Adults of e 18 years of age at the time of signing the informed consent.
- Diagnosis of Myasthenia Gravis with generalized muscle weakness, meeting clinical criteria for Myasthenia Gravis Foundation of America Class II to IVa classification.
- In participants positive for Acetylcholine receptor antibody (anti-AChR) or muscle-specific kinase antibody(anti-MuSK)
- In participants that are autoantibody seronegative and participants who are positive for anti-low-density lipoprotein receptor-related protein 4 antibodies (anti-LRP4)
- Has a Screening and Baseline MG-ADL score more than or equal to (\>=) 6 with \>= 50 percentage (%) of the total score due to non-ocular symptoms. Screening and Baseline MG-ADL scores must be stable. The difference between the Screening and Baseline scores should not be more than 2 and there should be no reported MG exacerbation during the Screening period

... and 3 more (see full listing online)

Exclusion (15)

- Immunologic disorder other than MG or any other condition requiring chronic oral, intravenous, intramuscular, or intraarticular corticosteroid therapy. Well-controlled thyroid disease, as per the Treating Investigator or the participants regular treating physician recorded in the source documents, is not exclusionary
- Molecularly characterized or suspected congenital myasthenic syndrome, Lambert-Eaton myasthenic syndrome, inherited myopathy, muscular dystrophy, acquired myopathy or any other neurologic or systematic disease that mimics MG muscular weakness
- Active, clinically significant viral, bacterial, or fungal infection, including brain MRI findings consistent with signs of infection such as PML, or any major episode of infection requiring hospitalization or treatment with parenteral anti-infectives within 8 weeks prior or during Screening, or completion of oral anti-infectives within 8 weeks prior or during Screening. Vaginal candidiasis, onychomycosis, and genital or oral herpes simplex virus considered by the Investigator to be sufficiently controlled would not be exclusionary
- Has a history of or current diagnosis of active tuberculosis (TB)
- Active malignancy, or history of cancer

... and 10 more (see full listing online)

Locations (132 total)

Arizona Neuroscience Research, LLC, Phoenix, Arizona, United States
Advanced Neurosciences Research LLC, Longmont, Colorado, United States
The George Washington University Medical Faculty Associates Foggy Bottom South Pavilion, Washington D.C., District of Columbia, United States
... and 129 more locations