

KYSA-6: A Study of Anti-CD19 Chimeric Antigen Receptor T-Cell Therapy, in Patients With Generalized Myasthenia Gravis

NCT06193889

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Kyverna Therapeutics
Enrollment	66 participants

Key Eligibility Criteria

Inclusion (10)

- Presence of autoantibodies to AChR or MuSK at screening.
- Myasthenia Gravis Foundation of America (MGFA) Class II-IV
- MG-Activities of Daily Living (MG-ADL) total score of e6 at screening and confirmed at pre-dose baseline
- QMG total score of e11 at screening and confirmed at pre-dose baseline
- Failed treatment with 2 or more immunosuppressive/immunomodulatory therapies, or failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, or IVIG (>4 times/year over e12 months) to control symptoms
- ... and 5 more (see full listing online)

Exclusion (9)

- Unable to washout or interrupt autoimmune disease therapy prior to apheresis
- Co-occurring neurological autoimmune disease (ie, Lambert-Eaton Myasthenic Syndrome) or any disease affecting the neuromuscular junction or muscle causing weakness (eg, myositis, myopathy, motor neuropathy)
- History of stroke (with residual sequelae and/or risk for recurrence), seizure (even if well controlled on antiepileptics), neurodegenerative disease, altered mental status (unexplained and/or recent/current), or uncontrolled/severe psychiatric disease
- Any serious and/or uncontrolled medical condition that, in the investigator's judgment, would cause unacceptable safety risk, interfere with study procedures or results, or compromise compliance with the protocol, including but not limited to, clinically significant cardiac or pulmonary disease
- History of primary immunodeficiency, organ or allogeneic bone marrow transplant, or splenectomy
- ... and 4 more (see full listing online)

Locations (14 total)

University of California, Irvine, Orange, California, United States
Stanford University Medical Center, Palo Alto, California, United States
University of Miami, Miami, Florida, United States
... and 11 more locations

<https://clinicaltrials.gov/study/NCT06193889>

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