GC012F Injection in the Treatment of Refractory Generalized Myasthenia Gravis(24103)

NCT07058298

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Daishi Tian
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (18)

- To be enrolled, subjects must meet all of the following criteria:
- Subjects or their legal representatives voluntarily sign a written informed consent and are willing and able to comply with the procedures of the study;
- Subjects aged 18-75 years old (both inclusive), male or female;
- Subjects with confirmed refractory gMG of classes IIa - IVb by MGFA clinical classification (including classes IIa, IIb, IIIa, IIIb, IVa and IVb) at screening;
- Subjects with the Myasthenia Gravis - Activities of Daily Living (MG-ADL) score of e6, the proportion of ocular symptoms of \<50% of the total score, and the Quantitative Myasthenia Gravis (QMG) score of e11;

... and 13 more (see full listing online)

Exclusion (32)

- Participants who meet any of the following criteria are not included in the study:
- Have a history of severe hypersensitivity or allergy;
- Contraindications or hypersensitivity to fludarabine, cyclophosphamide and any component of the test drug;
- Subjects who have received intravenous immunoglobulin or plasma exchange therapy or immunoadsorption therapy within 4 weeks prior to infusion;
- Received CD20-targeted drugs within 6 months prior to apheresis;

... and 27 more (see full listing online)

Locations (1 total)

Tongji Hospital of Tongji Medical Colledge, Huazhong University of Science and Technology, Wuhan, Hubei, China