

# Phase 4 Study Evaluating Efficacy and Safety of Rozanolixizumab in Adult Chinese Participants With Generalized Myasthenia Gravis

NCT07246564

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Status	RECRUITING
Phase	Phase 4
Sponsor	UCB Biopharma SRL
Enrollment	40 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Study participant must be ≥18 years of age at the time of signing the informed consent form (ICF)
- Study participant has documented diagnosis of generalized myasthenia gravis (gMG) at the Screening Visit based on study participant's history and supported by previous evaluation
- Study participant has a confirmed positive record of autoantibodies against acetylcholine receptor (AChR) or muscle-specific kinase (MuSK) documented in the medical history at the Screening Visit
- Study participant has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification II to IV at Screening Visit.
- Study participant with a myasthenia gravis-activities of daily living (MG-ADL) score of at least 3 points from non-ocular symptoms and a quantitative myasthenia gravis (QMG) score of at least 11 at the Screening and Baseline visits in the first Treatment Cycle.
- ... and 2 more (see full listing online)

### Exclusion (7)

- Study participant has a known hypersensitivity to any components of the study drug or any other anti-neonatal Fc receptor (anti-FcRn) medications
- Study participant has a clinically important active infection including unresolved or not adequately treated infection in the opinion of the investigator
- Study participant with a known tuberculosis (TB) infection, at high risk of acquiring TB infection, or latent tuberculosis infection (LTBI), or current/history of nontuberculous mycobacterial infection (NTMBI)
- Study participant has previously received rozanolixizumab drug product
- Study participant has received any vaccine in the 4 weeks prior to the initiation of rozanolixizumab treatment or intends to receive any vaccine within 2 weeks after the last infusion of rozanolixizumab. Note: For participants that are on rozanolixizumab treatment, vaccination with live or live-attenuated vaccines is not recommended. During the whole study period, all other vaccines should take place at least 2 weeks after the last infusion of a Treatment Cycle and 4 weeks before initiating the next cycle
- ... and 2 more (see full listing online)

## Locations (11 total)

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Mg0033 20040, Beijing, China  
Mg0033 20295, Changsha, China  
Mg0033 20348, Fuzhou, China  
... and 8 more locations

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<https://clinicaltrials.gov/study/NCT07246564>

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