# A Study of Nipocalimab in Children Aged 2 to Less Than 18 Years With Generalized Myasthenia Gravis

NCT05265273

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| **Status** | RECRUITING |
| **Phase** | Phase 2, Phase 3 |
| **Sponsor** | Janssen Research & Development, LLC |
| **Enrollment** | 12 participants |

## Key Eligibility Criteria

### Inclusion (7)

- Age: For US sites only: 8 to \< 18 years
- Diagnosis of myasthenia gravis (MG) with generalized muscle weakness meeting the clinical criteria for generalized myasthenia gravis (gMG) as defined by the Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class IIa/b, IIIa/b, or IVa/b at screening
- Has a positive serologic test for acetylcholine receptor (anti-AChR) antibodies or muscle-specific tyrosine kinase (anti-MuSK) antibodies at screening
- A participant using herbal, naturopathic, traditional Chinese remedies, ayurvedic or nutritional supplements, or medical marijuana (with a doctor's prescription) is eligible if the use of these medications is acceptable to the Investigator. These remedies must remain at a stable dose and regimen throughout the study
- Has sufficient venous access to allow drug administration by infusion and blood sampling as per the protocol

... and 2 more (see full listing online)

### Exclusion (5)

- Has a history of severe and/or uncontrolled hepatic (example, viral/alcoholic/ autoimmune hepatitis/ cirrhosis/ and/or metabolic liver disease), gastrointestinal, renal, pulmonary, cardiovascular (including congenital heart diseases), psychiatric, neurological musculoskeletal disorder, any other medical disorder(s) (example, diabetes mellitus), risk factors for thrombosis events (example, a history of venous thromboembolism \[VTE\] or antiphospholipid syndrome, or a personal or family history of heritable coagulation disorder such as factor V leiden, protein S or protein C deficiency, atrial fibrillation/flutter, major orthopedic surgery or significant trauma that may increase the risk of VTE, is expected to be immobilized for prolonged periods of time), or has clinically significant abnormalities in screening laboratory, that might interfere with participant's full participation in the study, and/ or might jeopardize the safety of the participant or the validity of the study results
- Has any confirmed or suspected clinical immunodeficiency syndrome not related to treatment of his/her generalized myasthenia gravis (gMG), or has a family history of congenital or hereditary immunodeficiency unless confirmed absent in the participant
- Has had a thymectomy within 12 months prior to screening, or thymectomy is planned during the Active treatment Phase of the study
- Has shown a previous severe immediate hypersensitivity reaction, such as anaphylaxis to therapeutic proteins (example, monoclonal antibodies)
- Has experienced myocardial infarction, unstable ischemic heart disease, or stroke within 12 weeks of screening

## Locations (19 total)

Phoenix Children's Hospital, Phoenix, Arizona, United States
Childrens Hospital Los Angeles, Los Angeles, California, United States
Lucile Packard Children's Hospital Stanford, Palo Alto, California, United States
... and 16 more locations