

# Study of Inebilizumab in Pediatric Subjects With Neuromyelitis Optica Spectrum Disorder

NCT05549258

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Status	RECRUITING
Phase	Phase 2
Sponsor	Amgen
Enrollment	15 participants

## Key Eligibility Criteria

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### Inclusion (3)

- Male or female participants, minimum body weight of 15 kg, age 2 to < 18 years at the time of screening.
- Positive serum anti-AQP4-IgG result at screening and diagnosed with NMOSD according to the criteria of Wingerchuk et al, 2015.
- Documented history of one or more NMOSD acute relapses within the last year, or 2 or more NMOSD acute relapses within 2 years prior to screening.

### Exclusion (38)

- Any condition that, in the opinion of the Investigator, would interfere with the evaluation or administration of the Investigational Product or interpretation of participant safety or study results.
- Concurrent/previous enrollment in another clinical study involving an investigational treatment within 4 weeks or 5 published half-lives of the investigational treatment, whichever is the longer, prior to Day 1.
- Evidence of significant hepatic, renal, or metabolic dysfunction or significant hematological abnormality (one repeat test may be conducted to confirm results within the same screening period).
- B-cell counts < one-half of the lower limit of normal (LLN) for age according to the central laboratory.
- Receipt of the following at any time prior to Day 1:  
... and 33 more (see full listing online)

## Locations (19 total)

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UCSD Altman Clinical and Translational Research Institute Building, La Jolla, California, United States  
Loma Linda University Children's Hospital - PIN, Loma Linda, California, United States  
Massachusetts General Hospital, Boston, Massachusetts, United States  
... and 16 more locations