

A Study To Evaluate Pharmacokinetics, Efficacy, Safety, Tolerability, And Pharmacodynamics Of Satralizumab In Pediatric Patients With Aquaporin-4 Antibody Positive Neuromyelitis Optica Spectrum Disorder (NMOSD)

NCT05199688

Status	RECRUITING
Phase	Phase 3
Sponsor	Hoffmann-La Roche
Enrollment	8 participants

Key Eligibility Criteria

Inclusion (7)

- Age at screening 2-11 years, inclusive
 - Body weight at screening ≥ 10 kg
 - For female patients of childbearing potential (postmenarchal): agreement to either remain completely abstinent (refrain from heterosexual intercourse) or to use a reliable means of contraception
 - Diagnosed as having NMOSD with AQP4 antibody seropositive status as defined by the Wingerchuk 2015 criteria Clinical evidence of at least one documented attack (including first attack) in the last year prior to screening
 - Neurological stability for ≥ 30 days prior to both screening and baseline
- ... and 2 more (see full listing online)

Exclusion (7)

- Pregnancy or lactation
 - Evidence of other demyelinating disease mimicking NMOSD
 - Active or presence of recurrent bacterial, viral, fungal, mycobacterial infection, or other infection at baseline
 - Evidence of chronic active hepatitis B or C
 - Evidence of untreated latent or active tuberculosis (TB)
- ... and 2 more (see full listing online)

Locations (12 total)

Children's Hospital Colorado., Denver, Colorado, United States
Hospital de Pediatría S.A.M.I.C.- Prof. Dr. Juan P. Garrahan, Ciudad Autonoma Buenos Aires, Argentina
Clinica Universitaria Reina Fabiola, Córdoba, Argentina
... and 9 more locations

<https://clinicaltrials.gov/study/NCT05199688>

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