

The Safety and Efficacy of NouvSoma001 in Neuromyelitis Optica Spectrum Disorders

NCT06620809

Status	RECRUITING
Phase	Phase 1
Sponsor	Tongji Hospital
Enrollment	69 participants

Key Eligibility Criteria

Inclusion (6)

- Patients must meet the 2015 International Consensus Diagnostic Criteria for Neuromyelitis Optica Spectrum Disorder (NMOSD) and test positive for AQP4 antibodies.
- Symptom onset occurred within 7 days prior to enrollment, with associated severe pain, lower limb motor dysfunction, or urinary/bowel impairment.
- Males or Females aged between 18 and 65 years.
- The Expanded Disability Status Scale (EDSS) score prior to the current disease episode is ≤ 4 .
- Female participants of childbearing potential must present a negative pregnancy test at screening and agree to use effective contraception throughout the study period.

... and 1 more (see full listing online)

Exclusion (16)

- Abnormal laboratory indicators of the subjects need to be excluded, including, but not limited to, the following indicators:
- White Blood Cell Count $\geq 3 \times 10^9/L$ Neutrophil Count $\geq 1.5 \times 10^9/L$ Hemoglobin ≤ 85 g/L Platelet Count $\leq 80 \times 10^9/L$ Serum Creatinine $> 1.5 \times ULN$ Total Bilirubin $> 1.5 \times ULN$ AST (GOT) $> 3 \times ULN$ ALT (GPT) $> 3 \times ULN$ Alkaline Phosphatase $> 2 \times ULN$ (AST = Aspartate Aminotransferase; GOT = Glutamic-Oxaloacetic Transaminase; ALT = Alanine Aminotransferase; GPT = Glutamic-Pyruvic Transaminase)
- Any contraindications to lumbar puncture.
- Pregnant or breastfeeding women, and patients with plans to conceive during the trial.
- Patients with a known history of allergies to human-derived biological products or those with an allergic predisposition.

... and 11 more (see full listing online)

Locations (1 total)

Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science and Technology, Wuhan, Hubei, China