Therapy in the Acute Phase of NMOSD: A Multicenter Prospective Real-World Study

NCT07410039

Status	RECRUITING
Phase	Phase 4
Sponsor	Chinese PLA General Hospital
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (7)

- Age: 18 - 65 years old, gender not restricted.
- Patients who meet the diagnostic criteria for NMOSD as set by the International Panel for NMO Diagnosis (IPND) in 2015, and have positive serum AQP4-IgG (by CBA method or live cell method).
- Acute phase of NMOSD-ON, defined as new or worsening optic nerve dysfunction (visual acuity decline accompanied or not by eye pain and visual field defect), with an onset duration of d 21 days, and clear evidence of new or recurrent optic nerve damage on imaging (new or expanded T2WI lesions, with enhancement); the best corrected visual acuity (BCVA) of the affected eye during the acute phase of NMOSD-ON (if both eyes are affected simultaneously, the worse eye is considered) drops from above 0.3 to d 0.1.
- Acute phase of NMOSD-TM, defined as new or worsening spinal cord dysfunction (limb weakness or numbness, accompanied or not by urinary and defecation disorders), with an onset duration of d 21 days, and clear evidence of new or recurrent spinal cord damage on imaging (new or expanded T2WI lesions, with enhancement); the EDSS score during the acute phase of NMOSD-TM increases from d 4.0 to e 6.0.
- Clinical onset and recurrence determination requires unanimous judgment by each center and the center committee (an independent group of 3 people).

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

Exclusion (15)

- Damage to the optic nerve or spinal cord caused by other non-NMOSD-related factors.
- Abnormal laboratory indicators that need to be excluded from the subjects include, but are not limited to the following indicators:
- Neutrophils \< 1.5 × 109/L, Hemoglobin \< 90g/L, Platelet count \< 75 × 109/L; Serum creatinine \> 1.5 × ULN, Total bilirubin \> 1.5 × ULN, Aspartate aminotransferase (AST) \> 1.5 × ULN, Alanine aminotransferase (ALT) \> 1.5 × ULN, Alkaline phosphatase \> 2 × ULN HbA1c \> 8% (for diabetic patients); GFR \< 60 mL/minute/1.73m2.
- Pregnant or lactating women, as well as those planning to become pregnant during the study period.
- Those who have received PE/IA/IVIG/FcRn/B-cell deletion/C5/IL-6 treatment within 1 month before enrollment.

... and 10 more (see full listing online)

Locations (1 total)

the First Medical Center of Chinese PLA General Hospital, Beijing, China