A Study Investigating Intravenous Human Normal Immune Globulin (IGIV) 10% in Subjects With Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

NCT06752356

Status	RECRUITING
Phase	Phase 3
Sponsor	Kedrion S.p.A.
Enrollment	161 participants

Key Eligibility Criteria

Inclusion (10)

- Male or female, aged e18 years.
- Written informed consent and authorization to access personal health information obtained independently from subjects indicating that they understand the purpose of, and procedures required for, the study and are willing to participate.
- Documented diagnosis of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) consistent with the 2021 EAN/PNS criteria.
- Current or documented history of significant disability, as defined by an overall adjusted INCAT disability score between 2 and 9. A score of 2 must be exclusively from the lower extremities.
- Subjects are currently dependent on treatment with immunoglobulins, corticosteroids, or standard of care treatments for CIDP.

... and 5 more (see full listing online)

Exclusion (37)

- Pure sensory atypical and multivariant CIDP.
- Females who are pregnant, breastfeeding, unwilling to practice adequate contraception throughout the study or planning a pregnancy during the course of the study.
- IG-experienced subjects requiring an IGIV dosage of more than 1.3 g/kg/month OR SCIG pre-treated subjects requiring a SCIG dosage of more than 1.6 g/kg/month.
- Subjects who have previously failed to respond to IGIV or SCIG.
- On screening date, a body mass index (BMI) \> 35 kg/m2 or an IGIV dose that puts the patient at risk of fluid overload.

... and 32 more (see full listing online)

Locations (1 total)

Advanced Neurology Epilepsy and Sleep Center/ANESC Research, El Paso, Texas, United States