

A Study Investigating Intravenous Human Normal Immunoglobulin 10% in Adults With Chronic Immune Thrombocytopenia (ITP)

NCT07059000

Status	RECRUITING
Phase	Phase 3
Sponsor	Kedrion S.p.A.
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (8)

- Male or female, 18-70 years of age.
- Patient and/or legal authorized representative has signed the ICF.
- Diagnosis of chronic (> 12 months duration) ITP as defined by the International Working Group.
- Mean screening platelet count of $< 30 \times 10^9/L$ from two qualifying counts measured at least one calendar day apart. The first qualifying count can be from historical data if measured within 14 days prior to the first KlG10 infusion. The second qualifying count will be measured within 7 days before the first KlG10 infusion.
- Platelet count of $< 30 \times 10^9/L$ at the Baseline Visit.

... and 3 more (see full listing online)

Exclusion (36)

- Patients with secondary ITP (all forms of immune-mediated thrombocytopenia except primary ITP). e.g., lupus erythematosus, rheumatoid arthritis, drug-related ITP, and Human Immunodeficiency Virus (HIV).
- Patients with Evans Syndrome.
- Patients known to be infected with hepatitis B virus, hepatitis C virus, or HIV.
- History of thrombotic events including deep vein thrombosis, cerebrovascular accident, pulmonary embolism, transient ischemic attacks, or myocardial infarction.
- Patient with a history of hypersensitivity to IVIg, other injectable forms of IVIg, or to any of the excipients.

... and 31 more (see full listing online)

Locations (27 total)

University of Southern California, Los Angeles, California, United States
East Carolina University, Greenville, North Carolina, United States
Vseobecna Fakultni Nemocnice v Praze, Prague, Prague, Czechia
... and 24 more locations