An Open-label Study of Intravenous Immunoglobulin (5%) for the Treatment of Primary Immune Thrombocytopenia

NCT07233213

Status	RECRUITING
Phase	Phase 3
Sponsor	Grand Shuyang Life Sciences (Chengdu) Co., Ltd.
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (5)

- At the time of signing the informed consent form, male or female patients aged e 18 years and d 65 years;
- Patients with clinically confirmed chronic ITP (i.e., the course of disease \> 12 months from diagnosis to signing the informed consent form);
- Patients who did not use glucocorticoids for at least 2 weeks before the first dose or used a maintenance dose of glucocorticoids for at least 2 weeks before the first dose, and did not plan to increase the dosage of glucocorticoids or add other platelet-elevating drugs within 4 weeks after the first dose;
- Platelet count \< 30 × 109/L;
- Patients who understand the procedures and methods of this study, are willing to sign the informed consent form and complete the study in strict accordance with the clinical study protocol.

Exclusion (28)

- Patients who are known or suspected to be allergic to human immunoglobulin or other plasma proteins and/or blood products, as well as excipients of the investigational drug, including those with a history of steroid hormone allergy;
- BMI e 30 kg/m2;
- Secondary thrombocytopenia;
- Patients with the following clinical manifestations or disease history at screening:
- Hemoglobin \<90 g/L or combined with immune hemolytic anemia;

... and 23 more (see full listing online)

Locations (9 total)

Hacettepe University Faculty of Medicine, Ankara, Alt1nda , Turkey (Türkiye)
0nönü University Turgut Ozal Medical Center Training and Research Hospital, Malatya, Battalgazi, Turkey (Türkiye)
0stanbul University, Istanbul Faculty of Medicine, Istanbul, Fatih, Turkey (Türkiye)
... and 6 more locations