TPO-RA in Primary Immune Thrombocytopenia (ITP) in Patients Older Than 14 Years

NCT04890041

Status	RECRUITING
Phase	Not Applicable
Sponsor	Institute of Hematology & Blood Diseases Hospital, China
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (4)

- Men and women greater than or equal to 14 years of age.
- Participants diagnosed with primary immune thrombocytopenia with two platelet counts of \< 30x10\^9/L or with bleeding at least 7 days apart do not have evidence of other causes of thrombocytopenia (e.g.,pseudothrombocytopenia, myeloid fibrosis).
- Previous treatment with poor response to first-line therapy and any of the maximum 4-week doses of eltrombopag, herombopag, avatrombopag, or 300U/kg/ day × 14-day rhTPO with no response to treatment (platelet count \< 30×109/L after treatment, or platelet count increase less than twice the baseline value, or with bleeding)
- Participants willing and able to comply with the requirements of the study protocol, and sign the informed consent.

Exclusion (8)

- Patients diagnosed with secondary immune thrombocytopenia.
- A history of arteriovenous thrombosis, disseminated intravascular coagulation, myocardial infarction, cerebral obstruction, thrombotic microangiopaemia, autoimmune diseases, malignant tumors, liver cirrhosis and other diseases that were not eligible for inclusion.
- Liver disease with one of the following indicators: a. total bilirubin e 2 times of the upper limit of normal; b. alanine aminotransferase (ALT) and aspartate aminotransferase (AST) e 2 times the upper limit of normal value; Patients with renal disease (serum creatinine e 1.5 times the upper limit of normal);
- Subjects with known allergies to eltrombopag, herombopag, rh-TPO, avatrombopag, or any of excipients;
- Have used rituximab in the past 3 months;

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

Locations (1 total)

Institute of Hematology & Blood Diseases Hospital, Tianjin, Tianjin Municipality, China