

Evaluate the Efficacy and Safety of Orelabrutinib in Adult Patients With Chronic Primary Immune Thrombocytopenia

NCT06004856

Status	RECRUITING
Phase	Phase 3
Sponsor	Beijing InnoCare Pharma Tech Co., Ltd.
Enrollment	195 participants

Key Eligibility Criteria

Inclusion (6)

- Subjects have had a detailed understanding of the nature, significance, possible benefits, possible inconveniences, and potential risks of the trial, understood the study procedures, and voluntarily signed a written ICF before the study.
 - Males or females aged from 18 to 80 years (including the marginal values).
 - With a body weight of e 35 kg at screening.
 - In accordance with the diagnosis of chronic (e 12 months) ITP
 - Patients who have previously received at least one anti-ITP first-line standard treatment (glucocorticoids and/or intravenous immunoglobulin) cannot maintain efficacy, or relapse, or cannot tolerate standard treatment, or have insufficient response.
- ... and 1 more (see full listing online)

Exclusion (19)

- Severe hemorrhage occurred within 4 weeks prior to screening.
 - Subjects suffered from severe ITP at screening and were not eligible for participation in this study as judged by the investigator.
 - Subjects had autoimmune systemic diseases other than ITP unless they would not affect the evaluation of the study results in the judgment of the investigator and sponsor medical monitor.
 - Subjects had multiple immune hemocytopenia.
 - Subjects had inherited thrombocytopenia or secondary ITP.
- ... and 14 more (see full listing online)

Locations (45 total)

The first affiliated hospital of bengbu medical college, Bengbu, Anhui, China
The First Affiliated Hospital of Anhui Medical University, Hefei, Anhui, China
Beijing CHAO-YANG Hospital Capital Medcal University, Beijing, Beijing Municipality, China
... and 42 more locations