

# Rituximab Combining Anti-CD38 Monoclonal Antibody Versus Rituximab in the Management of Primary Immune Thrombocytopenia (ITP)

NCT07234019

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Status	RECRUITING
Phase	Phase 2
Sponsor	Institute of Hematology & Blood Diseases Hospital, China
Enrollment	160 participants

## Key Eligibility Criteria

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### Inclusion (11)

- Age ≥18 years, male or female.
- Before enrollment, the subjects have been clinically diagnosed with primary immune thrombocytopenia for no less than three months according to the American Society of Hematology guidelines 2011 Evidence-Based Practice Guideline (Neunert et al. 2011) or the International Consensus Report for the Investigation and Management of Primary Immune Thrombocytopenia (Provan et al. 2010), as applicable locally.
- Subjects with a platelet count of  $<30 \times 10^9/L$  within the 48 hours prior to the first dose of the study drug; The platelet count of at least two separate assessments (at least 1 week apart)  $<30 \times 10^9/L$  during the screening visit.
- Patients have failed glucocorticoid therapy (either due to inefficacy, efficacy could not be maintained, or relapse).
- Previous emergency treatment for ITP (e.g., methylprednisolone, platelet, gamma globulin infusion) must have been completed at least 2 weeks before the first dose.

... and 6 more (see full listing online)

### Exclusion (15)

- Uncontrollable primary diseases of important organs, such as malignant tumors, liver failure, heart failure, renal failure and other diseases.
- HIV positive.
- Accompanied by uncontrollable active infection, including hepatitis B, hepatitis C, cytomegalovirus, EB virus and syphilis positive.
- Accompanied by extensive and severe bleeding, such as hemoptysis, upper gastrointestinal hemorrhage, intracranial hemorrhage, etc..
- At present, there are heart diseases, arrhythmias that need treatment or hypertension that researchers judge is poorly controlled.

... and 10 more (see full listing online)

## Locations (1 total)

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Chinese Academy of Medical Science and Blood Disease Hospital, Tianjin, Tianjin Municipality, China

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<https://clinicaltrials.gov/study/NCT07234019>

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