

Evaluating the Clinical Efficacy and Safety of Luspatercept Combined With Thalidomide in the Treatment of α TDT Patients

NCT07338344

Status	RECRUITING
Phase	Phase 2
Sponsor	Rongrong Liu
Enrollment	78 participants

Key Eligibility Criteria

Inclusion (6)

- Age \geq 18 years, regardless of gender;
- Patients with transfusion-dependent α thalassemia;
- Intended treatment with luspatercept combined with low-dose thalidomide or luspatercept alone;
- Requires regular red blood cell transfusions (6-30 RBC units (International Units) within 24 weeks prior to randomization, with a transfusion-free interval of \geq 42 days);
- ECOG performance status 0-1;
- ... and 1 more (see full listing online)

Exclusion (14)

- A diagnosis of β thalassemia minor, Hb Bart's edema, hemoglobin S/ β thalassemia, or myelodysplastic anemia (combination of α thalassemia and β thalassemia is permitted);
- Anemia related to nutritional deficiency, anemia of chronic disease, autoimmune hemolytic anemia, or any other hemolytic anemia (e.g., severe G6PD deficiency, pyruvate kinase deficiency);
- A bleeding disorder manifesting as frequent bleeding (e.g., menorrhagia, epistaxis, coagulopathy);
- Hemolysis unrelated to thalassemia within the past 8 weeks, such as after use of hemolytic-inducing medications (e.g., antimalarials, nonsteroidal anti-inflammatory drugs \[NSAIDs\]);
- Use of long-term anticoagulant therapy, unless discontinued at least 28 days before randomization. Prophylactic anticoagulant therapy for surgery or high-risk procedures, as well as low-molecular-weight heparin and long-term aspirin therapy for superficial venous thrombosis, are permitted.
- ... and 9 more (see full listing online)

Locations (8 total)

Southern Medical University Shenzhen Hospital, Shenzhen, Guangdong, China
Affiliated Hospital of Youjiang Medical College for Nationalities, Baise City, Guangxi, China
Baise People's Hospital, Baise City, Guangxi, China
... and 5 more locations

<https://clinicaltrials.gov/study/NCT07338344>

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