Evaluation of Safety, Efficacy, and Pharmacokinetics of BT-114143 Injection in Patients With Abnormal Uterine Bleeding

NCT07169214

Status	RECRUITING
Phase	Phase 1
Sponsor	ScinnoHub Pharmaceutical Co., Ltd.
Enrollment	39 participants

Key Eligibility Criteria

Inclusion (6)

- Be able to sign the informed consent form before any study-related procedures are performed, and be willing and able to comply with the study requirements;
- Premenopausal female subjects, aged 18-50 years, including 18 and 50 years;
- Have regular menstrual cycles in the past 6 months, with a menstrual cycle of e21 days and d35 days, and a menstrual period duration of d14 days;
- Meet the diagnosis of abnormal uterine bleeding and agree to be admitted for treatment. Assessed by the alkaline hemoglobin method, in 2 consecutive menstrual cycles during the screening period, the menstrual blood loss is \>80 ml in both cycles; or the blood loss in any one cycle is e160 ml;
- The pregnancy test result is negative before randomization;

... and 1 more (see full listing online)

Exclusion (28)

- Patients with known endometrial polyps \> 1.5 cm, endometrial malignancy, or atypical hyperplasia;
- Patients with known or investigator-determined ovulatory dysfunctional abnormal uterine bleeding who require hormonal therapy;
- Patients identified by investigators as having iatrogenic abnormal uterine bleeding;
- Patients with abnormal uterine bleeding related to coagulation dysfunction, including but not limited to those with laboratory test results showing: platelet count d 100×10y/L, or APTT prolonged by e 10s beyond the upper limit of normal, or PT prolonged by e 3s beyond the upper limit of normal;
- Patients with bleeding caused by cervical or vaginal lesions;

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

Locations (1 total)

Peking Union Medical College Hospital, Beijing, Beijing Municipality, China