A Study Evaluating the Effects of Itraconazole or Rifampin on the Pharmacokinetic Characteristics of Rocbrutinib Tablet

NCT07374224

Status	RECRUITING
Phase	Phase 1
Sponsor	Guangzhou Lupeng Pharmaceutical Company LTD.
Enrollment	28 participants

Key Eligibility Criteria

Inclusion (6)

• Subjects had no history of serious digestive system (such as inflammatory bowel disease, chronic diarrhea, Crohn's disease, autonomic dysfunction affecting gastric emptying), nervous system, cardiovascular system, genitourinary system, respiratory system, metabolic and endocrine system, musculoskeletal system, hematologic system diseases, or tumors

• Subjects must agree to complete abstinence or use effective physical contraception (including sterilization, intrauterine device or barrier contraception) from the time of signing the informed consent form until 90 days after the last dose of medication, and have no plans to donate sperm or eggs during this period; if female subjects are using hormonal contraceptives, they must stop using them \>14 days before the first dose and use at least one of the above contraceptive methods.

• Must be between 18 and 45 years old (inclusive) and be male or female when signing the informed consent form.

• Males weighing e50.0 kg or females weighing e45.0 kg, with a Body Mass Index (BMI) between 18.0 and 28.0 kg/m² (inclusive). BMI = weight (kg) / height² (m²).

• Able to understand and comply with the requirements of the research plan.

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

Exclusion (18)

• Abnormalities in screening tests, such as vital signs, physical examination, or laboratory tests are clinically significant and may increase the risk of participants participating in the study or affect the scientific validity of the study.

• Abnormal electrocardiogram or myocardial enzyme levels that are clinically significant as determined by a clinician include, but are not limited to: QTcF e 450 ms (corrected using the Fridricia formula, QTcF = QT/RR1/3, RR = 60/HR), etc.

• The test results for at least one of the following are positive: hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) antibody, human immunodeficiency virus (HIV) antibody, and syphilis-specific antibody.

• Patients who have taken the investigational drug within 4 weeks prior to or are required to take any drugs known to alter liver enzyme activity during the study period.

• The patient must have used any systemic medications (including any vaccines, prescription drugs, over-the-counter drugs, and traditional Chinese medicines), special medical purpose foods, or health supplements within two weeks prior to taking the investigational drug.

... and 13 more (see full listing online)

Locations (1 total)

Peking University Third Hospital, Beijing, Beijing Municipality, China