

A Trial of HRS-9813 in Healthy Subjects

NCT06821464

Status	RECRUITING
Phase	Phase 1
Sponsor	Guangdong Hengrui Pharmaceutical Co., Ltd
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (5)

- Voluntarily sign the informed consent form before the start of activities related to this trial, and be able to fully understand the procedures, methods, contents and possible adverse reactions of this trial, and be willing to strictly abide by the clinical trial protocol to complete this trial.
- Aged 18-45 years (inclusive), healthy male or female;
- Male weight \geq 50 kg, female weight \geq 45 kg, and body mass index (BMI): 19-26 kg/m² (inclusive), body mass index (BMI) = weight (kg)/(height/100)² (m²);
- Physical examination, vital signs, 12-lead electrocardiogram, chest anteroposterior and lateral radiographs, abdominal ultrasound and laboratory tests during the screening and baseline periods were normal, or slightly abnormal but clinically insignificant as determined by the researchers;
- Female subjects with fertility and male subjects whose partners are women of childbearing age have taken contraceptive measures within 2 weeks before signing the informed consent form, and are willing to abstain from sex or agree to contraception from the signing of the informed consent form until the end of the follow-up period (non-drug contraception is required during the trial, see Section 13.1.2 for details), and have no plans to have children or donate sperm/eggs.

Exclusion (28)

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 - The following diseases or treatment history:
 - Any serious clinical diseases such as urinary system, circulatory system, endocrine system, nervous system, digestive system, respiratory system, blood system, immune system, mental and metabolic disorders in the past or currently, or any other diseases that the investigators judge may interfere with the results of the trial, such as intestinal diseases (including irritable bowel syndrome) and urinary tract infection/stones, etc.;
 - History of malignant tumors (cancers that have been confirmed to have been cured or relieved for \geq 5 years, except for radically resected basal cell or squamous cell skin cancer, cervical cancer in situ and resected colon polyps);
 - Any conditions or diseases that affect the absorption, metabolism and/or excretion of the study drug;
- ... and 23 more (see full listing online)

Locations (1 total)

Shanghai General Hospital, Shanghai, Shanghai Municipality, China