

A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Food Effect of Single and Multiple Doses of HRS-3095 Oral Administration in Healthy Subjects, as Well as the Effect of HRS-3095 on CYP3A4 Metabolic Enzymes

NCT07230418

Status	RECRUITING
Phase	Phase 1
Sponsor	Chengdu Suncadia Medicine Co., Ltd.
Enrollment	66 participants

Key Eligibility Criteria

Inclusion (5)

- Able to comprehend and willing to sign an informed consent form (ICF);
- Male and female healthy subjects with an age range between 18 and 55 years (inclusive);
- Body mass index between 18.0 and 32.0 kg/m² (inclusive), and the body weight is \geq 50 kg for men and \geq 45 kg for women;
- For healthy subjects, no clinically significant abnormalities;
- Men and women of childbearing potential (WOCBP) must agree to take effective contraceptive methods.

Exclusion (4)

- Known medical history or clinical manifestation of circulatory, endocrine, neurological, digestive, respiratory, hematological, immunological, psychiatric diseases, metabolic disorders, or any other condition that may interfere with the trial results, as determined by the Investigator;
- Any condition or disease that may affect drug absorption, distribution, metabolism, or excretion, as determined by the Investigator;
- History of recurrent drug allergies, or a physician-diagnosed and treatment-requiring allergic disease, or known allergy to any component of the investigational product;
- History of an infection requiring systemic antimicrobial therapy within 2 weeks prior to screening or within 2 weeks before the first dose of the investigational product.

Locations (1 total)

The Frist Clinical Medical College of Qingdao University, Qingdao, Shandong, China

<https://clinicaltrials.gov/study/NCT07230418>

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