A Phase I Study of Single Subcutaneous Dose of SHR-1894 in Healthy Subjects

NCT07414602

Status	RECRUITING
Phase	Phase 1
Sponsor	Suzhou Suncadia Biopharmaceuticals Co., Ltd.
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (5)

- The subject has voluntarily provided written informed consent, fully understands the purpose and significance of this trial, and is willing to comply with the study protocol.
- Healthy male or female subjects, aged 18 to 45 years (inclusive) at the time of signing the informed consent form.
- Body weight e 50 kg for males and e 45 kg for females. Body mass index (BMI) = weight (kg)/height\^2 (m^2). BMI between 19 and 26 kg/m^2, inclusive.
- Subjects with no abnormalities, or only minor abnormalities deemed clinically insignificant by the investigator, in physical examination, vital signs, 12-lead electrocardiogram (ECG), posteroanterior and lateral chest radiographs, abdominal ultrasound, and laboratory tests during the screening and baseline periods.
- Female subjects of childbearing potential and male subjects with partners of childbearing age must have been using highly effective contraception for at least 2 weeks prior to signing the informed consent form. They must be willing to either abstain from sexual intercourse or agree to continue using highly effective contraception from the time of signing the informed consent until the end of the follow-up period, and must have no plans for conception or donation of sperm/ova.

Exclusion (14)

- Subjects with a history or current diagnosis of any clinically significant disease, as determined by the investigator, involving the urinary, circulatory, endocrine, neurological, digestive, respiratory, hematopoietic, immune systems, or psychiatric and metabolic disorders.
- Subjects who, in the investigator's judgment, have any condition or disease that may affect the absorption, metabolism, and/or excretion of the investigational drug.
- Subjects who have experienced severe infection, severe trauma, or undergone major surgery within 1 month prior to the screening period; or who plan to undergo surgery during the trial period.
- Subjects with a known allergy to the investigational drug or any of its components, or with a history of atopy (e.g., asthma, eczema).
- Subjects will be excluded if they meet any of the following criteria: Use of any medication (including prescription drugs, over-the-counter medications, Chinese herbal medicines, dietary supplements, and vitamin A and its derivatives, with the exception of other routine vitamins and occasional use of acetaminophen) within 2 weeks prior to screening.Any medication taken within 5 half-lives prior to screening (whichever period is longer).Planned use of any non-study medication during the trial period.

... and 9 more (see full listing online)

Locations (1 total)

West China Hospital of Sichuan University, Chengdu, Sichuan, China