

A Study of Safety, Tolerability, PK, and PD of Subcutaneous Gen-Sci136 in Healthy Adults.

NCT07366866

Status	RECRUITING
Phase	Phase 1
Sponsor	Changchun GeneScience Pharmaceutical Co., Ltd.
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (4)

- Male or female, aged 18 to 45 years (both inclusive) at the time of signing informed consent form (ICF).
- Male body weight \geq 50 kg or female body weight \geq 45 kg; BMI between 18-28 kg/m² (both inclusive) at screening.
- Males of reproductive age and females of childbearing potential must agree to take highly effective contraceptive methods from screening to the end of the study, and have no plans for conception, sperm donation, or egg donation; females of childbearing potential must have a negative pregnancy test at screening/baseline period and are not breastfeeding.
- Able to understand the trial procedures, voluntarily participate in the trial, understand and voluntarily sign the ICF, be able to follow all the trial requirements and complete the study.

Exclusion (6)

- Known hypersensitivity to GenSci136 or any of the excipients contained in the GenSci136 formulation, or history of serious hypersensitivity reactions to any drug, compound, food, or other substance, or an allergic constitution.
- Presence of tattoo, sunburn, scar or any other factors that may interfere with the assessment of the injection site at the intended injection area.
- A history or presence of other significant metabolic, dermatologic, hepatic, renal, hematologic, cardiovascular, gastrointestinal, psychoneurological, respiratory, and/or other major disease that, in the opinion of the investigator, would affect the evaluation of the study.
- Any major surgery within 3 months before screening, plan to undergo elective surgery during the study period, or have a history of any surgery that may affect the absorption, distribution, metabolism or excretion of the IMP.
- Positive result of alcohol breath test, or drug abuser, or use of soft drugs (such as marijuana) within 3 months prior to screening, or use of hard drugs (such as cocaine and ketamine) within 1 year prior to screening, or positive for drug screening \[including but not limited to morphine, ketamine, dimethyldioxyamphetamine, methamphetamine, tetrahydrocannabinol, and cocaine\].

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

Locations (1 total)

Huashan Hospital, Shanghai, Shanghai Municipality, China