Phase I Study of Single/Multiple Ascending Doses of JKN2501 for Injection in Chinese Healthy Volunteers

NCT07207291

Status	RECRUITING
Phase	Phase 1
Sponsor	Joincare Pharmaceutical Group Industry Co., Ltd
Enrollment	66 participants

Key Eligibility Criteria

Inclusion (5)

- Voluntary informed consent; able to comply with study requirements and communicate effectively.
- Healthy subjects aged 18-45 years (inclusive) at screening.
- BMI 19.0-26.0 kg/m² (inclusive); weight e50 kg (male) or e45 kg (female).
- Vital signs, physical examination, ECG, laboratory tests, chest X-ray, and abdominal ultrasound results judged as normal or clinically insignificant by the investigator.
- Agreement to use effective non-pharmaceutical contraception from signing ICF until 90 days after last dose; no sperm/egg donation plans during this period.

Exclusion (19)

- Pregnant/lactating women; positive pregnancy test; unprotected sex within 2 weeks prior to dosing.
- Investigator-determined history or presence of clinically significant disorder that may affect safety or trial participation.
- Use of drugs known to inhibit/induce hepatic metabolism within 4 weeks, or any medication (prescription, OTC, herbal, vitamins) within 2 weeks prior to dosing; planned use during the trial.
- Major surgery within 3 months prior to screening or planned during trial; history of surgery potentially affecting results.
- History of febrile illness or active infection within 2 weeks prior to screening.

... and 14 more (see full listing online)

Locations (1 total)

The Third hospital of Changsha, Changsha, Hunan, China