

A Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of SYH2070 Injection

NCT07241923

Status	RECRUITING
Phase	Phase 1
Sponsor	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (7)

- Subjects must provide informed consent before the trial, fully understand its content, procedures, and potential adverse reactions, and voluntarily sign the written ICF;
- Sex: Male or female;
- Age: 18-60 years (inclusive);
- Body mass index (BMI) in the range of 19 to 30 kg•m² \[BMI = weight/height² (kg•m²)\] (inclusive), with a weight of no less than 50 kg for males (inclusive) and no less than 45 kg for females (inclusive);
- Fasting serum TG ≤150 mg/dL (1.7 mmol/L) and ≤500 mg/dL (5.6 mmol/L), and LDL-C ≤70 mg/dL (1.8 mmol/L) and < 190 mg/dL (4.9 mmol/L) during the screening and baseline periods;
- ... and 2 more (see full listing online)

Exclusion (12)

- History of severe allergic diseases or allergic constitution (≥ 3 drug or food allergies), or known history of allergy to the investigational drug components (N-acetylgalactosamine, sodium hydroxide, phosphoric acid) or oligonucleotide drugs;
- Use of antibody drugs and/or oligonucleotide drugs targeting PCSK9/ANGPTL3/ApoC-III within 12 months prior to screening;
- Current and/or history of clinically significant medical conditions, including but not limited to circulatory, hematological or hematopoietic, respiratory, endocrine, urinary, digestive system diseases, neurological or psychiatric disorders, infections, tumors, severe trauma, or any other disease that should be excluded or may interfere with the interpretation of the study results, as judged by the investigator;
- History of major surgery within 6 months prior to screening, or are scheduled to undergo major surgery during the course of the study;
- History of bariatric surgery within 12 months prior to screening;
- ... and 7 more (see full listing online)

Locations (1 total)

Clinical Trials Information Group, Shijiazhuang, Hebei, China

<https://clinicaltrials.gov/study/NCT07241923>

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