

# Safety, Tolerability, PK and PD of SSS55 in Healthy Subjects

NCT07058779

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	Shenyang Sunshine Pharmaceutical Co., LTD.
<b>Enrollment</b>	26 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Healthy subjects aged 18 to 45 years old (including the boundary value), regardless of gender;
- The subjects voluntarily participated in the clinical trial and signed the informed consent form;
- Men with a weight of  $\geq 50$  kg, women with a weight of  $\geq 45$  kg, and those with a body mass index (BMI) ranging from 19 to 28 kg/m<sup>2</sup> (including the critical value);
- Those who underwent vital sign assessment, physical examination, blood routine, urine routine, blood biochemistry, coagulation function, pregnancy examination (for women of childbearing age), 12-lead ECG, chest X-ray/lung CT during screening, and the results showed no abnormalities or the abnormalities had no clinical significance;
- Be willing to receive the MV-ACYW meningococcal vaccine and pneumococcal vaccine 14 days or more before randomization.

### Exclusion (12)

- \) Those with a clear history of drug or food allergies, or a known history of hypersensitivity reactions that are clinically significant to the research intervention measures or related compounds or commonly used antibacterial agents;
- \) Those with a history of any serious clinical diseases in the past or present, including but not limited to those in the digestive system, cardiovascular system, respiratory system, urinary system, musculoskeletal system, endocrine system, immune system, neuropsychiatric system, hematological system, etc. (except those deemed eligible for enrollment by the researcher);
- \) First-degree relatives with a known history of meningococcal infection or a history of meningococcal infection;
- \) Those with contraindications to meningococcal vaccination (with a history of epilepsy or other brain diseases, etc.);
- \) There was or suspected active viral, bacterial, fungal or parasitic infection within 14 days prior to screening, including herpes, shingles or cold sores;

... and 7 more (see full listing online)

## Locations (1 total)

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Shanghai General Hospital, Shanghai, Shanghai Municipality, China