A Study to Describe the Safety and Immunogenicity of a Respiratory Syncytial Virus Vaccine IN006 in Healthy Adult Aged 18 Years and Above

NCT06645665

Status	RECRUITING
Phase	Phase 1
Sponsor	Shenzhen Shenxin Biotechnology Co., Ltd
Enrollment	240 participants

Key Eligibility Criteria

Inclusion (4)

- Healthy people aged 18-59 (Part 1) or e60 (Part 2), male or female.
- Body mass index (BMI) in the range of 18 to 29 kg/m\^2.
- Laboratory tests, 12-lead electrocardiogram, chest radiograph, vital signs and physical examination results are normal during the screening period, or abnormal results assessed by the investigator had no clinical significance; Subjects e60 years old with stable medical conditions, whose risk was considered controllable by the investigator, could also be enrolled.
- Women of childbearing age took effective contraception within 2 weeks before joining the study, and the pregnancy test results before vaccination are negative. All male and female subjects of reproductive age voluntarily agree to use effective contraception from the signing of informed consent until 6 months after vaccination.

Exclusion (24)

- The results of vital signs show: for subjects with no history of hypertension or hypotension, systolic blood pressure e140mmHg or \< 90mmHg, and/or diastolic blood pressure e90mmHg or \< 50mmHg; for subject with a history of hypertension not appropriately controlled via pharmaceutical treatment, systolic blood pressure e140mmHg or diastolic blood pressure e90mmHg in those aged 40-59, and systolic blood pressure e150mmHg or diastolic blood pressure e90mmHg in those aged 60 and above. Pulse rate \> 100 beats/min or \< 50 beats/min; Ear temperature/oral temperature \> 37.5°C (or axillary temperature \> 37.0°C).
- Laboratory tests, 12-lead electrocardiogram, chest radiography (orthographic) and physical examination results: For subjects aged 18-59 years old, abnormal results judged to be clinically significant by the investigator, or for subjects e60 years old, abnormal results judged to be \> Grade 1 criteria by the investigator; For laboratory tests, a retest may be conducted at the discretion of investigators to determine subjects eligibility.
- Those with tattoos, scars and ecchymosis at the injection site.
- Known allergy to the experimental vaccine or its excipient, or history of severe allergy to other vaccines, foods, drugs, etc.
- The subject has received any previous investigational or marketed RSV vaccine, or has received investigational or marketed RSV prophylactic monoclonal antibody within the last 6 months.

... and 19 more (see full listing online)

Locations (2 total)

Huashan Hospital Affiliated to Fudan University, Shanghai, Shanghai Municipality, China
Anning First People's Hospital, Kunming, Yunnan, China