Study to Evaluate the Safety and Immunogenicity of a Lyophilized Herpes Zoster Virus mRNA Vaccine

NCT07400003

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Sinovac Biotech Co., Ltd
Enrollment	519 participants

Key Eligibility Criteria

Inclusion (5)

- Phase I: Age e 40 years; Phase II: Age e 50 years;
- Participants are able to understand and voluntarily sign the informed consent form;
- Able to provide legal identification;
- Participants of childbearing potential and their sexual partners agree to voluntarily adopt effective contraceptive measures from the signing of the informed consent form until 6 months after the last dose of the investigational vaccine, with no plans for sperm or egg donation;
- Agree to comply with the visit schedule, sample collection, vaccination, and other trial procedures throughout the study period, and remain accessible at all times during the trial.

Exclusion (21)

- History of chickenpox or herpes zoster in adulthood;
- History of chickenpox or herpes zoster vaccination (including administration of registered products or participation in clinical trials of chickenpox or herpes zoster vaccines);
- Close contact with patients infected with chickenpox or herpes zoster within the past 30 days;
- Clinically significant abnormalities in protocol-specified clinical laboratory tests prior to vaccination (applicable to Phase I clinical trials only):
- A. Hematological parameters: White blood cell count (WBC), hemoglobin (Hb), platelet count (Plt); B. Blood biochemical parameters: Alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL), fasting blood glucose (Glu), creatinine (CR); C. Urinalysis parameter: Urine protein (PRO); D. Coagulation parameters: Prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (Fib), international normalized ratio (INR); E. 12-lead electrocardiogram (ECG).

... and 16 more (see full listing online)

Locations (1 total)

Xinjiang Uygur Autonomous Region Center for Disease Control and Prevention, Xinjiang, China