

A Clinical Trial of Rabies Vaccine Human Diploid Cell for Human Use, Freeze-dried

NCT07021703

Status	RECRUITING
Phase	Phase 1
Sponsor	Ningbo Rongan Biological Pharmaceutical Co., Ltd.
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (4)

- (1) The participants' ages range from 10 to 60 years old (≥10 years old and <61 years old).
- (2) Participants aged 10 to 17 and their guardians can provide valid identification documents, and participants aged 18 to 60 can provide their own valid identification documents.
- (3) Participants aged 10 to 17 and their guardians, as well as participants aged 18 to 60, can sign the informed consent form voluntarily to participate in the trial, fully understand the trial procedures, the risks of participating in the trial, and other intervention measures that can be chosen if they do not participate in the trial, etc.
- (4) Possess basic reading and writing skills, and be capable of reading, understanding and filling in diary cards and contact cards; (5) Female participants with fertility must also meet the following conditions: 1) They have taken effective contraceptive measures within two weeks prior to participating in this trial; 2) Have no plans to have children within 6 months from the start of participating in this trial until the full vaccination. 3) Understand and agree to take effective contraceptive measures during the trial period (from the first dose to within 6 months after the full vaccination). Effective contraceptive measures include: condoms (for men), intrauterine devices, oral contraceptives (excluding emergency contraceptives), sterilization, abstinence, injection or implantable contraception, sustained-release local contraceptives, hormone patches, diaphragms, cervical caps, etc. External ejaculation and safe period contraception are not regarded as effective contraceptive measures.

Exclusion (21)

- For the standards marked with *, if the participants have the circumstances stipulated in the standard, the visit can be rescheduled when they no longer have these circumstances
 - After inquiry, it is found that there is a history of rabies vaccination or the use of passive immunization preparations for rabies virus.
 - There was a history of injury from rabies virus-susceptible animals (such as cats and dogs) before the first dose of vaccination;
 - The axillary body temperature of the participants on the day of enrollment was ≥ 37.3 *;
 - Those whose various examination results during the screening period are abnormal and are determined by clinicians to be of clinical significance;
- ... and 16 more (see full listing online)

Locations (1 total)

Henan Provincial Center for Disease Control and Prevention, Zhengzhou, Henan, China