Safety and Immunogenicity of Recombinant Varicella Zoster Virus Vaccine in People With HIV Who Have a CD4 Count Less Than 300 or Greater Than or Equal to 300 and a Healthy Control Population

NCT05580458

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	225 participants

Plain Language Summary

This study is testing the safety and immune response to a shingles vaccine (recombinant varicella zoster virus vaccine) in people living with HIV, including those with lower immune cell counts (CD4 below 300) and those with higher counts. A healthy control group without HIV is also included for comparison.

You may be eligible if...
- You are 18 or older (for HIV-positive participants)
- You are HIV-positive and currently on antiretroviral treatment
- You have a primary care provider
- You are willing to use contraception if you can become pregnant
- Healthy volunteers (HIV-negative) may also be eligible

You may NOT be eligible if...
- You have previously had a severe allergic reaction to a varicella/shingles vaccine
- You have a condition or are taking medications that severely weaken your immune system (beyond HIV itself)
- You are pregnant or planning to become pregnant during the study
- Other safety-related reasons determined by the study team

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (18)

- Individuals must meet all of the following criteria to be eligible for study participation:
- Able to provide informed consent.
- Participants of childbearing potential must agree to use at least 1 acceptable method of contraception when engaging in sexual activities that can result in pregnancy, beginning at screening through month 3. Acceptable methods of contraception include the following:
- Hormonal contraception.
- Male or female condom.

... and 13 more (see full listing online)

Exclusion (16)

- Individuals meeting any of the following criteria will be excluded from study participation:
- Previous receipt of Shingrix vaccine at any time.
- Receipt of Zostavax within the past 12 months.
- History of severe allergic reaction to any component of Shingrix.

• Diagnosed varicella or herpes zoster episode within the past 1 month. Subject will be eligible for SHINGRIX vaccine once symptoms of herpes zoster episode have resolved.

... and 11 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States