

Trial to Evaluate Immunogenicity Non-Inferiority, Safety and Lot-to-Lot Consistency of Biovac OCV-S to Euvichol®-Plus

NCT07304284

Status	RECRUITING
Phase	Phase 3
Sponsor	International Vaccine Institute
Enrollment	2,824 participants

Key Eligibility Criteria

Inclusion (7)

- Healthy participants aged 1 to 45 years at consent
- Participants/Parent(s)/Legally Authorized Representative (LAR) willing to provide informed consent/assent
- HIV negative
- Not pregnant or lactating
- PLWH adults aged 18 to 45 years at consent

... and 2 more (see full listing online)

Exclusion (10)

- Known history or allergy to investigational vaccine components, other preventive vaccines, or any other allergies
- Individuals with major congenital abnormalities
- Known history of immune function disorders including immunodeficiency diseases (known HIV infection in healthy participant cohorts) or other immune function disorders (all cohorts).
- Use of systemic steroids within past 6 months (>10 mg/day prednisone equivalent for periods exceeding 2 consecutive weeks), or receive chemotherapy, radiation therapy or other immunosuppressive drugs within the past 6 months.
- Behavioral or cognitive impairment, chronic substance abuse, or psychiatric disease or neurological disorders.

... and 5 more (see full listing online)

Locations (5 total)

Synergy Biomed Research Institute, Durban, Eastern Cape, South Africa
Perinatal HIV Research Unit (PHRU), Johannesburg, Gauteng, South Africa
Wits Vaccines & Infectious Diseases Analytics (VIDA) Research Unit, Johannesburg, Gauteng, South Africa
... and 2 more locations