A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection
Inclusion Criteria
General and Demographic Criteria

• Age 18 – 50 years
• Access to a participating CRS
• Ability & Willingness to provide informed consent
General and Demographic Criteria

- Agrees not to enrol in another study
- Volunteer demonstrates understanding of this study
- Good general health
  - As shown by medical history, physical exam, and screening laboratory tests
HIV-Related Criteria

• Willingness to receive HIV test results
• Willingness to discuss HIV infection risks and amenable to HIV risk reduction counselling
• In Africa, persons born Female (assigned female sex at birth) and identifying as a female
  • Who, in the 6 months prior to randomization, has had vaginal and/or anal intercourse with a male partner.
  • All volunteers who have been in a monogamous relationship with an HIV-1 seronegative partner for > 1 year are excluded
Inclusion Criteria

- HIV uninfected, within 30 days prior to enrolment.
- Not pregnant
- Hemoglobin (Hgb) > 10.5 g/dL
- Platelets: ≥ 100,000 cells/mm³
- ALT < 2.5 ULN
- Negative, trace, or 1+ urine protein by dipstick
Exclusion Criteria
General

- Investigational research agents received within 30 days before first infusion
- Body mass index (BMI) ≥ 40 kg/m²
- Exclusion Criteria: Monoclonal antibodies and vaccines
  - Previous receipt of humanized or human mAbs
  - HIV vaccine(s) received in a prior HIV vaccine trial
Immune System

- Serious adverse reactions to VRC01 formulation components
  - Such as sodium citrate, sodium chloride, and L-arginine hydrochloride
- Autoimmune disease
- Immunodeficiency syndrome
Clinically significant medical conditions

- Any medical, psychiatric, occupational, or other condition
  - in the judgment of the investigator, would interfere with, or serve as a contraindication to, protocol adherence, assessment of safety or infusion reactions, or a volunteer’s ability to give informed consent.
- Psychiatric condition that precludes compliance with the protocol
- Asthma
- Bleeding Disorder
Clinically significant medical conditions

- Malignancy
- Seizure Disorder
- Angioedema
  - History of hereditary angioedema, acquired angioedema, or idiopathic angioedema.
- Organ or tissue transplantation
- Known hepatic or renal dysfunction
Clinically significant medical conditions

• Clinically significant medical condition
  • Physical examination findings, clinically significant abnormal laboratory results, or past medical history with clinically significant implications for current health.
Thank you