Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	HVTN 140/HPTN 101
Scientific Title	A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, and pharmacokinetics of PGDM1400LS alone and in combination with VRC07-523LS and PGT121.414.LS in healthy, HIV-uninfected adult participants

Primary Sponsor Details

Sponsors *	National Institutes of Health

Secondary Sponsor Details

Contact for Public Queries

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Affiliation	University of Zimbabwe Clinical Trials Research Centre

Contact for Scientific Queries

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Countries of Recruitment *

Kenya, South Africa, USA and Zimbabwe

Source of Funds	United States of America, National Institute of Health
Health Condition(s) or Problem(s) Studied *	HIV
Medicine Name *	PGDM1400LS (Sterile solution for injection, formulated at a concentration of 100 mg/mL in a buffered solution of 10 mM acetate, 9% (w/v) sucrose, 0.01% (w/v) polysorbate 80 at a pH of 5.2)
Quantity of medicine required *	PDGM1400LS X 18 vials

7.0 PRINCIPAL INCLUSION CRITERIA *

Inclusion criteria

- **Age of 18 through 50 years**
- **Access to a participating CRS and willingness to be followed for the planned duration of the study**
- **Ability and willingness to provide informed consent**
- **Assessment of understanding: volunteer demonstrates understanding of this study and completes a questionnaire prior to first study product administration with verbal demonstration of understanding of all questionnaire items answered incorrectly**
- **Agrees not to enroll in another study of an investigational research agent until completion of the last required protocol clinic visit.**
- **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 counseling.**
- **Assessed by the clinic staff as being at "low risk" for HIV infection and committed to maintaining behavior consistent with low risk of HIV exposure through the last required protocol clinic visit**

7.1 PRINCIPAL EXCLUSION CRITERIA *

Exclusion criteria

- **Weight < 35kg or > 115 kg**
- **Blood products received within 120 days before first study product administration, unless eligibility for earlier enrollment is determined by the HVTN 140/HPTN 101 PSRT**
- **Investigational research agents received within 30 days before first study product administration**
- **Intent to participate in another study of an investigational research agent or any other study that requires non-Network HIV antibody testing during the planned duration of the HVTN 140/HPTN 101 study**
- **Vaccines, Antibodies, and other Injections or Infusions**
- **HIV vaccine(s) received in a prior HIV vaccine trial. Volunteers who have received control/placebo in an HIV vaccine trial are not excludedHVTN 140/HPTN 101.**
- **SARS-CoV-2 vaccine(s) received within 7 days prior to HVTN 140/HPTN 101 enrollment or planned within 7 days after enrollment.**
- **Receipt of humanized or human mAbs, whether licensed or investigational.**
- **Previous receipt of mAbs VRC01, VRC01LS, VRC07-523LS, PGDM1400, PGT121, PGT121.414.LS.**
- **Immunosuppressive medications received within 30 days before first study product administration (Not exclusionary: [1] corticosteroid nasal spray; [2] inhaled corticosteroids; [3] topical corticosteroids for mild, uncomplicated dermatological condition; or [4] a single course of oral/parenteral prednisone or equivalent at doses < 20 mg/day and length of therapy < 14 days)**
- **Serious adverse reactions to PGDM1400LS, VRC07-523LS, or PGT121.414.LS formulation components, including history of anaphylaxis and related symptoms such as hives, respiratory difficulty, angioedema, and/or abdominal pain.**
- **Immunoglobulin received within 60 days before first study product administration (for mAb see criterion 8 above**

7.2 PRIMARY END POINTS *

Early discontinuation of administration and reason(s) for discontinuation and early study termination

Local and systemic Solicited AEs, laboratory measures of safety, Unsolicited AEs, and SAEs

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled
If controlled	
Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	Yes
Cross over	No
Other	No
If yes to other, specify	

If controlled, specify the comparator	Placebo controlled
Other medicinal product(s)	No
Placebo	Yes
Other	No
If yes to other, specify	
Other	No

Expected Number of participants in Zimbabwe *	24
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	6
Total participants worldwide *	95

Time period for the trial *	14 months