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HIV Prevention
Trials Network

HPTN081/HVTN703/AMP Study Lessons Learnt

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Study Design and Duration

- **A phase 2b double blind Placebo controlled study to evaluate the efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection**

Study Rationale

- Passive administration of VRC01 antibody will reduce acquisition of HIV infection in high risk populations;
- Doses selected will determine the activity of the antibody across a range of serum concentration in diverse populations across multiple geographic regions of the world;
- Level of VRC01 antibody required for protection will vary by type of sexual exposure;
- Concentration of antibody in serum will be directly associated with the rate of protection; that is, higher levels of antibody will give greater rates of protection than lower levels; and
- Breakthrough isolates will have greater resistance to neutralization and will exhibit molecular signatures associated with escape from neutralization.

Study Objectives

PRIMARY

- Safety & Tolerability of VRC01 infusion
  - Reactogenicity, AEs, SAEs, discontinuation rates
- Efficacy to prevent HIV infection
  - HIV infection by week 80 in those HIV-negative at enrollment

SECONDARY

- Develop a marker(s) of VRC01 that correlates with the level and antigenic specificity of efficacy
  - Serum VRC01 concentration
  - Serum mAb effector functions
  - Breakthrough HIV viral sequences in infected people
  - VRC01 neutralization sensitivity of, & effector functions against, HIV strains from infected trial participants

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Study Population and Size

Cohort	Antibody (VRC 01) 10mg/kg	Antibody (VRC 01) 30mg/kg	Placebo	Total Population
Americas*: United States, Peru & Brazil MSM & TG people (Clade B)	800	800	800	2,400*
Southern Africa: Botswana, Kenya, Malawi, Mozambique, South Africa, Tanzania, Zimbabwe Heterosexual women (Clades A, C, D, & CRFs)	**500**	**500**	**500**	**1,500**
Total*	1,300	1,300	1,300	3,900*

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Clinical Research Sites

- Gabarone, Botswana
- Kisumu, Kenya
- Blantyre, Malawi
  Lilongwe, Malawi
  Maputo, Mozambique
- Harare (3 clinics), Zimbabwe
- Mbeya, Tanzania

Cape Town, RSA
Durban (4 clinics), RSA
Johannesburg, RSA
Soweto, RSA
Vulindlela, RSA
Rustenberg
Klerksdorp
Pretoria
Tembisa

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Gaborone CRS

- Started screening -21 July 2016
- First Enrolment-16 Aug 2016
- Screened to date - 141 (March 30, 2017)
- Enrolled to date - 52 (March 30, 2017)
- Average screenings per week-3.6
- Average enrolments per week-1.5

Recruitment

- First contact?

-utilized existing established relationships with clinics

-contacted participants from previous studies

-visited tertiary institutions

-collaborations with HTC organizations

Challenges and Solutions

- Some participants willing to join study but partners/parents not too sure
  - ✓ we are open to participant bringing in significant others
  - ✓ more information dispels myths about research

Challenges and Solutions

- Contraception
  - ➢ women not on hormonal contraception
    - fear of side effects
  - ✓ we partnered with an organization which provides FP services

Challenges and Solutions

- Women come as group
  - If one decides not to enroll, ALL go
  - ✓To about individual

Retention Strategies

- All our participants still on study
  - Bringing significant others
  - Bringing babies
  - Wifi
  - Snack
  - Televison??
  - Small talk about how study going
  - CAB members interaction with study participants

Community Engagement

- Continuous CE with various stakeholders
- Use of recruitment material
- Piggy back on national/local events
- Maintenance of established referral system with HTC organizations and advocacy groups
  - Periodic updates including successes and challenges
  - Effort recognition of individual organization

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Stakeholders – MoH, Clinics

Community Members

HTC and other service organizations

Community and Religious leaders