HVTN 704/HPTN 085

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Who are we?
Who are we?

- Located in Newark, NJ
- Funded in 2007 as 1 of 10 Clinical Research Sites in the Terry Beirn CPCRA CTU (Fred Gordin, MD, PI)
- Re-funded in 2013 as Joint CTU with Well-Cornell Medical Center (Trip Gulick, MD, PI)
- Current clinical research activity: ACTG, INSIGHT, HPTN, pharma and investigator initiated studies
- Co-located in the Infectious Disease Practice (IDP)
What is AMP?

• AMP stands for Antibody Mediated Prevention

• Using an antibody against HIV that was made in a lab and given to people as an intravenous infusion

• “IV” or “getting a drip”
Study Rationale

- https://www.youtube.com/watch?v=e91JxLxZIimg
Multicenter, randomized, controlled, double-blind trial
- 21 months of scheduled clinic visits
  - 10 infusions

<table>
<thead>
<tr>
<th>Infusion schedule (Weeks)</th>
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<tr>
<td>Cohort</td>
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<tr>
<td>Group 1</td>
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<tr>
<td>North + South American + Euro MSM &amp; TG</td>
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<td>Group 2</td>
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<td>Group 3</td>
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Study Design and Duration
Study Objectives

- **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

- **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
Study Population and Size

• N=2700
• 18-50 years old
• HIV-1- uninfected MSM and TG persons who have sex with men or TG persons
Clinical Research Sites
Clinical Research Sites

United States
- Atlanta, GA (2 clinic locations)
- Birmingham, AL
- Boston, MA (2 clinic locations)
- Chapel Hill, NC
- Cleveland, OH
- Los Angeles, CA
- Nashville, TN
- **Newark, NJ**
- New York City, NY (4 clinic locations)
- Philadelphia, PA
- Rochester, NY
- San Francisco, CA
- Seattle, WA
- Washington, DC

South America
- Peru (4 sites)
- Brazil

Switzerland
Current Study Status

• 31 March 2016
  – Protocol Opened

• 06 Apr 2016
  – 1st Participant Enrolled

• 04 Apr 2017
  – 958 Participants Enrolled
  – 24 Participants Randomized
Newark Enrollment Status

• 330 Potential Candidates
• 26 Jul 16
  – First Participant Enrolled
• 50 Candidates Consented
• 13 Failed Screening
  – 5 Preliminary Positive Results
  – 2 Diabetes
  – 1 ALT >2.5XULN
  – 1 BMI >40
  – 2 Medical History
  – 2 Sexual Risk

• 35 Enrolled
  – 2 pending
What is Community Engagement?
Community Engagement

- Conversations
- Meetings
- Community Partners
- Gatekeepers
- Local Businesses/Hangouts
- Site Staff
- Participants
- Community Leaders
- Local, National, International Awareness
- Engagement Domains
- Strategy
- Consistency
- Transparency
- Adaptability

Domains:
- Awareness
- Engagement
- Consistency
- Strategy
Engagement Domains

- Retention
- Education
- Support
- Recruitment
Education

• Provide information about research studies
• Share interactive videos about study rationale and procedures
• Discuss HIV prevention methods and the current state of research
• Review Truvada as PrEP, safer sex practices, sex positive messages
• Other topics as needed or requested by CBOs or other organizations/groups

• Goals
  – Raise awareness about HIV and prevention studies
  – Provide knowledge about HIV, methods of transmission and other sexual health related topics
  – Establish our site as an ally and resource to community
Recruitment

- Presentation directed and provided to target population in group facilitated or discussion setting
- Study specific recruitment materials (ie. business cards, chochkis, pre-screeners) are available
- Some education is provided but focus is on engaging potential clients to be pre-screened, discussing HIV prevention research, and focusing on being a part of the next phase of HIV prevention

- **Goal**
  - ENROLLMENTS!
Retention

• Activities focused on maintaining interest in study participation as well as ensuring our participants are appreciated for their participation
  – Events are informal and do not involve study specific information or presentations

• Goals
  – Encourage retention in our study activities and adherence to schedule of events
  – Foster sense of community among participants and staff
Support

Activities engage NJMS CRC staff with the populations we serve by attending local events without actively recruiting
- Houseball competitions
- Facilitated discussions
- Task force meetings

Goals
- Collaborative efforts
- Foster sense of community
- Remain connected to local events and cultural shifts
ACKNOWLEDGEMENTS

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