MTN-009
Prevalence of HIV-1 drug resistance within a female screening population for HIV prevention trials

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BUILDING A HEALTHY NATION THROUGH RESEARCH

Objectives

Primary Objective:

- To assess the frequency of HIV drug resistance mutations among women who test HIV-positive when presenting to screen for participation in HIV prevention trials

Primary Endpoint:

- Major and minor mutations in HIV-1 reverse transcriptase and protease known to be associated with drug resistance as measured by standard and sensitive genotypic methods

Objectives cont…

Secondary Objectives:

- To identify and evaluate behavioral indicators including self or sexual partner(s) exposures to antiretroviral drugs as risk factors for drug resistant HIV infection in women who present for screening to participate in HIV prevention trials
- To characterize the degree of immunodeficiency and risk of disease progression by quantifying plasma HIV-1 RNA and CD4-positive T cells among women who test HIV-positive when presenting for screening to participate in HIV prevention trials

Objectives cont….

Secondary Endpoints:

- Participant self-reported antiretroviral drug exposures and other behaviors of herself or sexual partner(s) that may be associated with risk of drug resistant HIV infection
- Plasma HIV-1 RNA levels and CD4-positive T-cell counts

Study Hypothesis

The prevalence of HIV drug resistance in the population of women interested in participating in HIV prevention trials who are found to be HIV positive will be low and underestimated by standard genotyping methods.

Study Design

- This study will provide an estimate of the prevalence of ARV resistance in the population of women who present to study sites to be pre-screened or screened for participation in an HIV prevention trial.
- This study uses a cross-sectional design.
- Descriptive characteristics of the infection and behavioral information, including self- reported ARV exposure of the participant and her sexual partner (s) will be collected.
- All participants who present to MTN-009 study sites for pre-screening or screening for HIV prevention trials will be offered participation in MTN-009
- Based on local estimates of the HIV prevalence rates, approximately 1000 participants may need to be recruited in order to reach 350 evaluable HIV-positive participants for the primary endpoint

Summary Schema for MTN-009 Enrollment in the Context of Screening fo

HIV Prevention Trials

MTN-009 is presented to a woman interested in screening for an HIV prevention trial.

Willing to participate

Not willing to participate

Refer to HIV Prevention Trial

Administrative and Regulatory Procedures

Behavioral Questionnaire

2 HIV Rapid Tests
Finger prick

HIV NEG
-/-

HIV POS
+/+

Discordant
+/-

Western Blot
Inform NL

Laboratory Tests
(blood specimen collection as needed)

Laboratory procedures

Personnel

Visit 1 **HIV POS** → Blood draw (20ml) — **Nurse**

↓ HPRU Central Routine Laboratory

CD4 count (HPRU Central Routine lab)(1ml)
Plasma storage (viral load; resistance testing NL) (5x1.8ml aliquots) — **Med Tech**

↓ 1 week TAT

Visit 2 Provision of CD4 result — **Nurse/Clinician**

↓

Management of OIs
Management of Bactrim prophylaxis and multivitamins — **Clinician**

Ongoing counseling for HIV secondary infections
STI risk reduction — **Nurse**

↓

>350 T cell count

<350 T cell count
DOH referral for Wellness and pre-ART initiation — **Clinician**

Laboratory procedures cont….

Visit 3

6- 8 weeks TAT
NL

Provision of viral load; resistance results
(chronic or recent using current incidence testing algorithms)

Clinician

Visit 4

VL and resistance result available to ppt to guide ART management
(<350 T cell count DOH referral for Wellness and pre-ART initiation;
>350 T cell count on-going counseling as required)

Clinician

Advantages:
Streamline MTN-003
Provision of CD4 T cell count and VL results

Referral to DOH

Potential challenges:
Need staff categories
Nurse
RA
Counselor
Clinician

MTN-003
if no ppt

THANK YOU