MTN-016

HIV Prevention Agent Pregnancy Exposure Registry

Protocol Co-Chairs:
Richard Beigi, MD, MSc
Magee-Womens Hospital, Pittsburgh USA
Samuel Kabwigu, MBChB, MMED
Makerere University, Kampala Uganda
MTN-016

EMBRACE: Evaluation of Maternal and Baby Outcomes Registry After Chemoprophylactic Exposure
Study Population

- Participants who become or became pregnant during HIV prevention trials, or who have or had planned exposures in pregnancy safety studies, provided pregnancy outcome was <1 year from the date of the EMBRACE Screening/Enrollment Visit
  - Target enrollment = 500 women

- The infants resulting from those pregnancies, provided infants have not yet reached their 1 year birth date.
  - Target enrollment = 300 live infants
MTN-016: EMBRACE

Primary Objectives

- Pregnancy loss: mothers exposed/not exposed to an active study agent
- Major malformations: infants exposed/not exposed to active study agent \textit{in utero}
MTN-016: EMBRACE

Secondary Objectives
- Adverse pregnancy outcomes
- Growth parameters: infants exposed/not exposed to active study agent \textit{in utero}
- Major malformations: infants exposed/not exposed to active study agent \textit{in utero}

Exploratory Objectives
- Select risks of prevention agents by trimester of exposure
- Prevalence/persistence of HIV drug mutations in HIV-infected infants
- Developmental screening: infants exposed/not exposed to active study agent \textit{in utero}
MTN-016: EMBRACE

Expected MTN parent protocols:

- **MTN-002: Ph 1 Maternal Single-Dose PK and Placental transfer of Tenofovir 1% Vaginal gel among Healthy Term Gravidas**

  - N = 16 mother-infant pairs

- **MTN-008: Expanded Safety Investigation of Tenofovir 1% Gel in Pregnancy and Lactation**

  - N = 90 mother-infant pairs

- **MTN-003: VOICE**

  - Expected to contribute the remainder
MTN016 Participant Contributors

- Kampala
- Durban: 7 sites
- Johannesburg: PRHU, RHRU, Aurum
- Harare: 3 sites
- eThekwini
- Durban: 7 sites
- Birmingham
- Pittsburgh
MTN-016: EMBRACE

Main Maternal Inclusion Criterion
- During participation in parent protocol, has/had known confirmed pregnancy

Maternal Exclusion Criteria
- Any condition that would complicate study outcome data
- Pregnancy outcome diagnosed > 1 yr ago
MTN-016: EMBRACE

Main Infant Inclusion Criterion
- Born to mother enrolled in EMBRACE

Infant Exclusion Criteria
- Any condition that would complicate study outcome data
- Has reached 1 year birth date
MTN 016: EMBRACE

Maternal Visit Schedule
- Screening/Enrollment
- Quarterly
- (Pregnancy Outcome)

Infant Visit Schedule
- Newborn/Initial Visit
- Months 1, 6 and 12
MTN-016 Sites: 12 of 17

- Pittsburgh, US
- Zimbabwe – 3 sites
- MRC, Durban, SA – 7 sites
- Uganda

- RHRU
- PHRU
- eThekwini
- Aurum
- Birmingham, Alabama, US
GOAL

All 17 sites activated prior to January, 2011

PREFERABLY ... NOVEMBER 30, 2010