INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

A CROSS-SECTIONAL AND PROSPECTIVE, OBSERVATIONAL, COHORT STUDY TO ESTIMATE HIV INCIDENCE AMONG SEXUALLY ACTIVE ADULT FEMALES

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PROTOCOL SYNOPSIS

TITLE

A Cross-sectional and Prospective, Observational, Cohort Study to Estimate HIV Incidence among Sexually Active Adult Females.

OBJECTIVES

Primary Objective:

- To estimate HIV incidence among sexually active adult females.

Secondary Objectives:

- To describe demographic characteristics, HIV risk behaviors, contraceptive use, sexually transmitted infection/reproductive tract infection (STI/RTI) symptomatic diagnoses, vaginal hygiene practices, and use of vaginally applied products among sexually active adult females.
- To provide on-site Good Clinical Practice (GCP) training and experience to site staff in preparation for conducting future HIV prevention clinical trials using vaginal microbicide products.
- To estimate accrual and retention of women who might participate in future microbicide clinical trials.
- To estimate the incidence rate of pregnancy in the study population when provided on-site contraceptive counseling and contraceptives.

ENDPOINTS

HIV is the primary endpoint for the study. HIV incidence from cross-sectional data will be calculated. HIV incidence rate from the prospective cohort data will compute the number of HIV-1 seroconversions and person-time follow-up.
The secondary endpoints will be summarized by descriptive data and statistics; tables and listings; retention rates will be calculated and an incidence rate for pregnancy and STI/RTI symptoms will be computed.

DESIGN

This is a cross-sectional and prospective, observational cohort study to estimate HIV incidence in sexually active adult females. The cross-sectional study component, with a sample size of 800 women, will estimate HIV incidence using the BED IgG-capture enzyme immunoassay (BED CEIA) and Abbott AxSYM HIV 1/2gO Avidity index assays to detect recent HIV infections from blood collected from HIV seropositive women at the screening visit. In addition, 300 of the screened subjects who are HIV seronegative will be enrolled into a prospective cohort study for a 12-month follow-up period and observed for HIV seroconversion.

STUDY POPULATION

Females ≥18 and ≤ 35 years of age who are currently sexually active and meet study eligibility criteria.