Background

- Phase II trial of daily oral tenofovir disoproxil fumarate (TDF), oral TDF/emtricitabine (FTC), and vaginal tenofovir (TFV) gel for HIV-1 prevention (Fig 1).
- Conducted in 2009-2012 among African women followed for 12-18 months (Fig 2).
- Intent-to-treat analysis showed no protective effect of TFV detection (≥0.3 ng/mL) measured in plasma samples collected at baseline (Fig 2).

Methods

- Plasma TFV detection provides an objective measure of product use and correlates with efficacy.4,5
- In previous PEPFAR trials, product use correlated with sites, demographic, behavioral, psychosocial & clinical factors.4-8
- TFV detection was predictive of laser ablation, as well as TFV gel take.
- VOICE participants randomized to active products (oral  group (TDF, FTC/TDF) and TFV gel group).

Study Objectives

- VOICE: Participants randomized to active products (oral group: (TDF, FTC/TDF) and TFV gel group).
- Study objectives:
  - Determine PIN (primary ITT analysis), and plasma TFV detection.
  - Characteristics by study group.
  - Table 2: Summary: Factors associated with plasma PK detection at Q1.
  - Table 3: Summary: Factors associated with plasma PK detection at Q1.

Results

- Table 1: Characteristics by study group.
- Table 2: Summary: Factors associated with plasma PK detection at Q1.
- Table 3: Summary: Factors associated with plasma PK detection at Q1.
- Table 4: Oral group - TFV detection.
- Table 5: Gel group - TFV detection.

Correlates of Early Adherence in VOICE PrEP Trial Differ Between Oral and Vaginal Products

Ariane van der Straten,1 Elizabeth R. Brown,1 James DAI,2 Craig R. Hendrix,2 Karen Liu,4 Cynthia Grossman,3 Zvavahera M. Chirenje,6 and Jeanne M. Marrazzo2 for the VOICE team.

Women's Global Health Imperative, RTI International, San Francisco, CA, USA; 1University of Washington, Seattle, WA, USA; 2Johns Hopkins University, Baltimore, MD, USA, 3CHAIHP-FHOIC, Seattle, WA, USA; 4National Institute of Mental Health, Bethesda, MD, USA, 5U-CF Collaborative Research Programme, Harare, Zimbabwe

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More Information

*Presenting author: Ariane van der Straten
415-846-1327
ariane@rti.org

RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

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