Safety and pharmacokinetic assessment of 28 day anti-HIV dapivirine intravaginal microbicide rings


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Dapivirine Intravaginal Rings for Prevention of HIV Transmission

- Dapivirine (NNRTI) IVRs were used for 28 days by healthy, HIV-negative women 18-35 yrs
- Adverse events possibly related were similar in dapivirine and placebo IVR groups
- No clinically relevant changes from baseline
- Drug was effectively distributed throughout genital tract (cervicovaginal fluids) at concentrations 10^4-fold (reservoir) to 10^6-fold (matrix) greater than EC_{90} (0.9ng/mL)
- Terminal half-life in vaginal fluids was 15-16 hrs
- Systemic exposure to dapivirine was low (C_{max} 1.21 ng/mL for matrix and 0.05 ng/mL for reservoir)

Annalene Nel, MD; International Partnership for Microbicides; Silver Springs, MD USA
Conclusions – Discussion Points

- Dapivirine IVRs were safe and well tolerated for 28 days in HIV-negative women.
- Matrix rings deliver the highest dose in tissues.
- Pharmacokinetic data support future development as monthly-dosed microbicide.
- Microbicide use is female controlled.
- Monthly replacement of IVR may increase product adherence and efficacy.

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