

**Risk factors associated with HIV incidence in HSV-2 seropositive Tanzanian women in a RCT of HSV-2 suppressive therapy**

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**Background:** A randomized placebo-controlled trial (RCT) of HSV-2 suppressive therapy conducted between 2004-2007 reported a similar rate of HIV acquisition in both trial arms. Risk factors associated with HIV incidence are examined in the context of 3 monthly follow-up visits offering both VCT and STI care.

**Methods:** 821 HSV-2 seropositive, HIV seronegative female bar, hotel and other facility workers aged 16-35 years were randomized to acyclovir 400 mg BD (N=400) or placebo (N=421) and followed every 3 months for 12 to 30 months, depending on date of enrolment. The primary outcome was HIV incidence. Risk factors and rate ratios for HIV acquisition were estimated with Cox regression.

**Results:** In total, 659 women (80%) completed follow-up. HIV incidence was 4.27 per 100 person-years overall, and 10.3 per 100 person-years in 16- 19 year olds. There was no impact of acyclovir on HIV incidence (RR=1.01; 95%CI 0.61-1.66). HIV acquisition was associated with younger age (adjusted RR=3.95; 95%CI 1.64-9.49 for 16-19 y vs ≥30y), having a paying sexual partner in past 3 months (adjusted RR=1.81; 95%CI 1.08-3.03), alcohol (≥10 drinks/week: adjusted RR=3.27; 95%CI 1.72-6.22), injections outside the study clinic within the previous 3 months (adjusted RR=3.46; 95%CI 1.63- 7.36) and recent infection with gonorrhoea (adjusted RR=3.63; 95%CI 1.63-8.10). There was a borderline association between HIV and living in that study community for <2 years (adjusted RR=1.76; 95%CI 0.99-3.13) and using hormonal contraception (adjusted RR=1.59; 95%CI 0.93-2.75).

**Conclusions:** A high incidence of HIV was observed in this trial cohort, especially in young women. Interventions are needed to address the risk associated with alcohol and to sustain control of other STIs. Further work is needed to examine the role of injections and hormonal contraception.

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