

Abstract

TUPE0418 - Progress of a randomised trial of HSV-2 suppressive treatment for HIV prevention in northern Tanzania

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Background: Tanzanian women working in bars, hotels and other facilities comprise a group at high risk of HIV and HSV-2 infection. HSV-2 infection is associated with HIV acquisition and increased HIV genital viral shedding. An HSV suppressive therapy trial is underway in Tanzania to determine whether aciclovir (ACV) will reduce (1) HIV incidence in initially HIV negative women and (2) HIV genital shedding in HIV positive women.

Methods: A double-blind, randomised placebo-controlled trial of HSV-2 suppressive therapy with ACV 400mg bd is being conducted in HIV+ and HIV- facility workers. Women are screened for HIV and HSV2 antibodies. HSV2+ eligible women are enrolled and randomised to ACV or placebo and followed for up to 30 months, depending on date of enrolment. Adherence is measured through pill counts, self-reporting and random urine testing of ACV metabolites.

Results: 2113 women were initially screened, of whom 1669 (79.0%) were HSV-2 antibody positive. 1001 women were randomised of whom 383 (38.3%) were HIV seropositive. Overall, 85%, 77%, 71% and 71% attended and were still on study tablets at the 3, 9, 12 and 15 month visits respectively. 18% have been withdrawn from study tablets, and this proportion was similar among HIV seropositive and seronegative women. A further 300 women are currently being enrolled and cohort follow-up has been extended because of a lower than expected HIV incidence and a higher than anticipated pregnancy rate. At 3, 9 and 12 months visits, at least 75% of tablets had been taken in the preceding 3 months by 75%, 84% and 87% of women respectively.

Conclusions: Female facility workers have been successfully recruited but additional women are being enrolled because of a lower than expected HIV incidence. Preliminary analysis suggests that adherence assessed by tablet counting has improved with time. Pregnancy is the main reason for withdrawal from study tablets.