Results 156 (105 women and 51 men) healthy, immunocompetent, HSV-2 positive participants with a history of 1–9 recurrences per year prior to trial entry, or previous suppressive therapy, were randomised by seven US sites between May 2010 and October 2010. 147 completed the trial. Overall, about 9000 swabs for HSV PCR were collected and assayed for HSV DNA by a sensitive and accurate assay that can detect >150 copies/ml. The first results of these assessments will be presented.

Conclusion The trial will provide insight into the antiviral activity of the novel agent AIC316 for genital HSV infections. This trial design presents a robust and efficient method for evaluating antiviral activity of candidate agents for mucocutaneous HSV infections. These initial efficacy and safety results will lead to selecting the dose for further trials with AIC316.

FREQUENT BREAKTHROUGH GENITAL HSV-2 SHEDDING ON STANDARD AND HIGH DOSE VALACYCLOVIR

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Background Short, rapidly cleared, subclinical shedding episodes are the predominant form of HSV-2 reactivation in the genital tract. Valacyclovir 500 mg once daily (SD-VAL) reduces the risk of sexual transmission of herpes simplex virus type 2 (HSV-2) by only 48%. We hypothesised that short HSV-2 shedding episodes occur frequently on SD-VAL and that high dose (HD)-VAL could suppress such episodes of genital HSV-2 shedding.

Methods A randomised open-label crossover study using valacyclovir 500 mg daily (SD-VAL) vs valacyclovir 1 gm three times daily (HD-VAL) was conducted in HSV-2 seropositive, HIV seronegative persons with four or more genital herpes recurrences per year or laboratory confirmed primary genital HSV-2 infection in the previous 6 months. Each study arm lasted for 5 weeks, separated by 1 week wash out. Participants obtained genital swabs four times daily, which were assayed for HSV by quantitative PCR. The primary outcome was frequency of genital HSV shedding on each study arm; secondary outcomes included number and duration of HSV-2 shedding episodes and quantity of virus detected.

Results Forty-three participants collected 9981 genital swabs during the study period. 292 (5.8%) of 5008 swabs had HSV detected during SD-VAL, compared to 164 (3.3%) of 4973 on HD-VAL (IRR = 0.52, 95% CI: 0.45 to 0.63, p < 0.001). Episodes were shorter on HD-VAL (median 7 h, compared to 10 h on SD-VAL, p = 0.03) and the median maximum copy number was lower on HD-VAL (3.0 log10 copies/ml vs 2.5 log10 copies/ml, p = 0.001). However, the annual episode rate was the same regardless of dose; there were 55 shedding episodes over 5.59 person-years of follow-up during SD-VAL (14.1 episodes/year) and 65 episodes over 5.95 person-years during HD-VAL (16.5 episodes/year, p = 0.54).

Conclusion Short bursts of genital HSV-2 reactivation persist during SD-VAL and HD-VAL. Compared to SD-VAL, HD-VAL decreased shedding frequency and episode duration but did not alter episode rate. These data may explain why risk of HSV transmission and HSV-specific genital inflammation persist even in the presence of antiviral therapy. More potent therapies are needed to completely suppress HSV-2 reactivation.

Clinical Trials.gov number NCT00362297.

THE POST-TRIAL EFFECT OF PERIODIC PRESUMPTIVE TREATMENT FOR VAGINAL INFECTIONS ON THE INCIDENCE OF BACTERIAL VAGINOSIS AND LACTOBACILLUS COLONISATION

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Background Bacterial vaginosis (BV) is a highly prevalent infection that frequently recurs following standard treatment. In a randomised controlled trial (RCT) of oral periodic presumptive treatment (PPT) to reduce vaginal infections among Kenyan women, we observed a decrease in BV and an increase in Lactobacillus colonisation among women randomised to receive 2 g metronidazole +150 mg fluconazole monthly for 12 months. After the trial,