

## **ABSTRACT**

### ***BACKGROUND:***

Vaginal infections are common, frequently recur, and may increase women's risk for sexually transmitted infections (STIs). We tested the efficacy of a novel regimen to prevent recurrent vaginal infections.

### ***METHODS:***

HIV-negative women 18-45 years old with one or more vaginal infections including bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), or *Trichomonas vaginalis* (TV) were randomly assigned to receive vaginal suppositories containing metronidazole 750mg plus miconazole 200mg or matching placebo for five consecutive nights each month for 12 months. Primary endpoints, evaluated every 2 months, were BV (Gram stain) and VVC (positive wet mount and culture).

### ***RESULTS:***

Participants (N=234) were randomly assigned to the intervention (N=118) or placebo (N=116) arm. Two-hundred and seventeen (93%) women completed an end-of-study evaluation. The intervention reduced the proportion of visits with BV compared to placebo (21.2% versus 32.5%; relative risk [RR] 0.65, 95% confidence interval [CI] 0.48-0.87). In contrast, the proportion of visits with VVC was similar in the intervention (10.4%) versus placebo (11.3%) arms (RR 0.92, 95%CI 0.62-1.37).

### ***CONCLUSIONS:***

Monthly treatment with intravaginal metronidazole plus miconazole reduced the proportion of visits with BV during 12 months of follow-up. Further study will be important to determine whether this intervention can reduce women's risk of STIs.