

ASPIRE and The Ring Study Results – A Snapshot

| Study | <u>The Ring Study (IPM 027)</u> International Partnership for Microbicides | <u>ASPIRE (MTN 020)</u> Microbicide Trials Network |
|---|---|---|
| <i>Study design and enrollment</i> | | |
| <i>Objectives</i> | Long term safety and effectiveness | Safety and effectiveness |
| <i>Study design</i> | Double blind randomized placebo controlled with 2:1 randomization (active: placebo) | Double blind randomized placebo controlled with 1:1 randomization (active: placebo) |
| <i>Enrollment</i> | Total: 1959 women, ages 18-45 Active arm: ~1300 | Total: 2629 women, ages 18-45 Active arm: ~1325 |
| <i>Regulatory requirement</i> | 3000 women on dapivirine ring for at least 1 year follow-up 1500 women on dapivirine ring for 2 year follow-up | |
| <i>Participant follow-up</i> | 2 years + 6 weeks following ring discontinuation | Minimum 1 year + 4 weeks following ring discontinuation |
| <i>Research sites</i> | 7 IPM research center partners in South Africa and Uganda | 15 MTN research centers in Malawi, South Africa, Uganda, Zimbabwe |
| <i>*Results</i> | | |
| <i>Overall results</i> | 31% effective, confidence interval 1-51 | 27% effective, confidence interval 1-46 |
| <i>Secondary analysis that excluded data from 2 sites with lower retention and adherence</i> | | 37% effective, confidence interval 12-56 |
| <i>*Results by age stratification (post hoc analysis)</i> | | |
| <i>Women over 21 years of age</i> | 37% effective, confidence interval 3.5-59 | 56% effective, confidence interval 31-71 |
| <i>Women 18-21 years of age</i> | No statistically significant effect | No statistically significant effect |
| <i>*HIV incidence</i> | | |
| <i>Overall</i> | 4.1% among women in active arm 6.1% among women in placebo arm | 3.3% among women in active arm 4.5% among women in placebo arm |

*Please take a look at our “[Advocates’ Guide to Statistical Terms](#)” to better understand the results