

HPTN 059: Daily vs. Coitally Dependent PMPA Gel

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HPTN 059: Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1% PMPA Gel

Primary objective –

- To assess the local and systemic safety of PMPA gel for vaginal use in HIV-uninfected women versus a placebo gel over 24 weeks of daily and coitally dependent use

Secondary objective –

- Acceptability and adherence to, two regimens of study gel use in women

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Exploratory objectives –

- To measure vaginal flora characteristics, and to descriptively examine changes in these characteristics over the course of prolonged study gel use
- To assess the effects of study gel on cytokine and chemokine expression in cervical secretions
- To evaluate the association between cytokine and chemokine expression
- To correlate cytokine and chemokine expression with colposcopic evidence of inflammation and epithelial disruption

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- Study population: 200 sexually active HIV negative women with normal lower genital tract
- Women randomized to coitally dependent or daily use of placebo vs. 1% PMPA gel
- Product to be applied at least 2 hours before each act of intercourse in the coitally dependent group
- Maximum use of gel: twice daily

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- Status: currently enrolling in Pune India, and Birmingham, AL and Bronx Lebanon in NY
- Recruitment finalized in Pune India March 13, 2007

Site	Date of First Enrollment	Total No. Screened	Total No. Enrolled
NARI	August 24, 2006	116	100
BLHC	August 11, 2006	92	42
UAB	August 9, 2006	67	39
Total	NA	275	181

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- Accrual of patients was 6½ months in Pune India which was very close to the target of six months
- Recruitment had to be curtailed at both domestic sites due to a problem with gel availability and packaging which caused a slow down in recruitment
- Recruitment at domestic sites will be completed in April 2007.

Highlights of HPTN 059 Progress as of March 8, 2007

- Inappropriate enrollment: 0
- Completed visits per protocol
 - » 4 week: 144/146 (97%)
 - » 8 week: 117/119 (98%)
 - » 12 week: 91/98 (93%)
 - » 16 week: 67/72 (93%)
 - » 20 week: 40/41 (98%)
 - » 24 week: 11/11 (100%)

Highlights of HPTN 059 Progress

Adherence to Gel Product

<u>Condom</u>	<u>N</u>	<u>Gel Used</u>	
		Yes	No
Used	312	296 (95%)	16 (5%)
Not Used	42	25 (60%)	17 (40%)

Karen Patterson of SCHARP says, “the data quality is outstanding”