MTN 044 - PK Study of 90-Day Use of Vaginal Rings Containing Dapivirine and Levonorgestrel
Data as of December 1, 2025

Screen-out Summary by Site

	Pittsburgh, PA	All Sites
Participants Screened[1]	52	52
Participants Enrolled[2, 3]	25 (48%)	25 (48%)
Participants not Enrolled	27 (52%)	27 (52%)
Participant did not complete all screening procedures[4]	0 (0%)	0 (0%)
Participant is eligible but did not enroll	0 (0%)	0 (0%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)
Participant not eligible[5]	27 (100%)	27 (100%)
Not assigned female sex at birth	0 (0%)	0 (0%)
Not in the age 18 through 45 years	0 (0%)	0 (0%)
Not able and unwilling to provide written informed consent	0 (0%)	0 (0%)
Not able and unwilling to provide adequate locator information	0 (0%)	0 (0%)
Not able to communicate in spoken and written English	0 (0%)	0 (0%)
Not available for all visits abd unwilling to comply with all study procedural requirements	9 (33%)	9 (33%)
Unwilling to abstain from receptive intercourse and tampon use for 24 hours	0 (0%)	0 (0%)
Not at risk for pregnancy and unwilling to use,a non-hormonal method of contraception during study participation	1 (4%)	1 (4%)
Not at good health as determined by the Investigator of Record (IoR)/designee at Screening and Enrollment	3 (11%)	3 (11%)
HIV-infected based on testing performed at Screening and Enrollment	0 (0%)	0 (0%)
Irregular menstrual cycles	3 (11%)	3 (11%)
Does not have intact uterus	0 (0%)	0 (0%)
States a unwillingness to refrain from inserting any non-study vaginal products or objects into the vagina for 24 hours	0 (0%)	0 (0%)
Participants less than the age of 21 and does not have a documentation of a satisfactory PAP within the past 3 years	0 (0%)	0 (0%)
Disagrees not to participate in other research studies involving drugs,medical devices,vagainal products or vaccines	0 (0%)	0 (0%)
Body mass index greater than 40 kg/m2	2 (7%)	2 (7%)
Pregnant at screening or enrollment or plans to become pregnant	0 (0%)	0 (0%)
Diagnosed with symptomatic urinary tract infection(UTI) or reproductive tract infection(RTI)	0 (0%)	0 (0%)
Diagnosed with an acute STI requiring treatment per current CDC guideliness	2 (7%)	2 (7%)
Has a clinically apparent Grade 2 or higher pelvic exam finding	0 (0%)	0 (0%)
Known adverse reaction to any component of the study product	0 (0%)	0 (0%)
Chronic or recurrent vagianl candiasis	0 (0%)	0 (0%)
Has a contradiction to a progestin only contraceptive methos as defined by category 3 or 4 condition	0 (0%)	0 (0%)
Use of hormonal contraception, including hormonal IUD and implants within the 28 days	0 (0%)	0 (0%)

[1] Number of participants screened is based on the Inclusion Exclusion eCRF, and may differ from the Enrollment report, which is instead based on the Scr Date of Visit eCRF.
[2] Number of participants enrolled is based on the Inclusion Exclusion eCRF, so could differ from the Enrollment report, which is instead based on the Enrollment eCRF.
[3] Percentage of participants screened.
[4] Percentage of participants not enrolled.
[5] Participants may be ineligible for more than one reason.

Source: SCHARP (Gayathri) - /trials/mtn/p044/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (02DEC2025,6:52)

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Current use or planned use of CYP3A inhibitors and inducers	1 (4%)	1 (4%)
Current use or planned use of antibiotics and/or corticosteroids that may interact with levonorgestrel	0 (0%)	0 (0%)
Depot medroxyprogesterone acetate(DMPA) use in the 6 months	0 (0%)	0 (0%)
Non-therapeutic injection drug use in the 12 months	0 (0%)	0 (0%)
Post-exposure prophylaxis (PEP) for HIV exposure within the 3 months	0 (0%)	0 (0%)
Pre-exposure prophylaxix(PREP) for HIV prevention within the 3 months	0 (0%)	0 (0%)
Last pregnancy outcome less than 60 days	0 (0%)	0 (0%)
Gynecologic or genital procedure (e.g. tubal ligation,dilation and curettage,piercing) 45 days or less	0 (0%)	0 (0%)
Currently breastfeeding or planning to breast feed	0 (0%)	0 (0%)
Participation in any other research study involving drugs,medical devices,vaginal products or vaccines in the 60 days	0 (0%)	0 (0%)
Grade 1 or higher AST or ALT laboratory abnormalities	0 (0%)	0 (0%)
Grade 1 or higher Creatinine laboratory abnormalities	0 (0%)	0 (0%)
Grade 1 or higher Hemoglobin laboratory abnormalities	0 (0%)	0 (0%)
Other conditions	6 (22%)	6 (22%)

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Pittsburgh, PA	Determined screen fail due to various PI concerns about whether she would be able to complete study.
2		Participant cancelled enrollment visit and then did not return contacts to reschedule.
3		Ppt not able to comply with comply with study schedule and visit appointments as she did not show up to her enrollment visit.
4		irregular cycles
5		Unable to draw participant's blood due to poor venous access.
6		Participant had a positive Trichomonas test; participant also had a breast mass that the PI deemed as making her ineligible.
7		Participant tested positive for Chlamydia at screening
8		Participant was no longer willing to have cervical biopsies performed
9		Ppt unable to provide cycle length, provided 2 different birthdays during visit and had difficulty recalling med hx/medications/dosages. Concern about following procedures and reporting accurate data.
10		BMI was 42.0
11		Ppt had recent visit to ED and outpatient visits vor varying problems and complaints, including ongoing dizziness, passing out and involuntary movements. Ppt currently being worked up for these sympto
12		Ppt had an ER visit for stroke like symptoms on 2/28/19, and has been seen by neurology a few times since then and has had a battery of tests without a clear diagnosis.
13		Screen fail due to investigator's discretion. After reviewing after the screening visit, the PI reviewed the medical history of a uterine ablation and little bleeding with menses since then.
14		PI discretion due to history of anxiety/depression and suicidal ideation.
15		Due to family health problems, had to cancel her enrollment visit and is unable to reschedule at this time
16		The participant is no longer able to comply with the study schedule and visit windows.
17		electronic medical records entry for irregular menses. Also, multiple psychiatric ED visits were noted.
18		Change in contraceptive method, no longer abstinent.
19		Participant reports no longer being willing/able to do study
20		Participant now unable to complete study schedule due to her job.
21		Participant gave conflicting medical history. Decision was made to screen fail her after labs were already sent in for testing; tested positive for GC and Trich
22		Participant had a BMI at screening of 41.4
23		Ppt not eligible due to uncontrolled hypertension.
24		Participant does not have regular menstrual cycles, with cycle lengths often inconsistent and over 35 days
25		Participant currently takes fluoxetine
26		There are concerns about participant's ability to complete study text messaging, as well as complete visits within window
27		Due to a new obligation, the participant was no longer able to complete visit schedule.