MTN 030 - Pharmacokinetic and Safety Study of Dapivirine/Levonorgestrel Vaginal Rings
Data as of December 1, 2025

Screen-out Summary by Site

	All Sites	Birmingham, AL	Pittsburgh, PA
Participants Screened	40	20	20
Participants Enrolled[1, 2]	24 (60%)	12 (60%)	12 (60%)
Participants not Enrolled	16 (40%)	8 (40%)	8 (40%)
Participant did not complete all screening procedures[3]	0 (0%)	0 (0%)	0 (0%)
Participant is eligible but declined enrollment	1 (6%)	1 (13%)	0 (0%)
Participant is eligible but acrual closed prior to enrollment	4 (25%)	1 (13%)	3 (38%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[4]	11 (69%)	6 (75%)	5 (63%)
Ineligible due to exclusion[5]	7 (64%)	5 (71%)	2 (50%)
Body mass index greater than 35 kg/m2 at Screening	3 (27%)	2 (33%)	1 (20%)
Pregnant at screening or Enrollment or plans to become pregant during the study period	0 (0%)	0 (0%)	0 (0%)
Diagnosed with a urinary tract infection or reproductive tract infection at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)
Diagnosed with an acute sexually transmitted infection required treatment per current CDC gudeliness at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)
Has a clinically apparent Grade 2 or higher pelvic examination finding at Screening or Enrollment	0 (0%)	0 (0%)	0 (0%)
Known adverse reaction to any of the study products (EVER)	0 (0%)	0 (0%)	0 (0%)
Chronic and/or recurrent vaginal candidiasis	0 (0%)	0 (0%)	0 (0%)
Has a contraindication to progestin-only contraceptive method	0 (0%)	0 (0%)	0 (0%)
Use of hormaonal contraception,includiong hormonal IUD within the 28 days	0 (0%)	0 (0%)	0 (0%)
Current used or planned use of CYP3A inhibitors and inducers	0 (0%)	0 (0%)	0 (0%)
DMPA use in the 6 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Non-therpeutic injection drug use in the 12 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
PEP for HIV exposure within the 6 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
PrEP for HIV prevention within the 6 months prior to Enrolllment	0 (0%)	0 (0%)	0 (0%)

[1] Number of participants enrolled is based on the eligibility criteria eCRF, so could differ from the accrual report, which is instead based on the randomization eCRF.
[2] Percentage of participants screened.
[3] Percentage of participants not enrolled.
[4] Participants may be ineligible for more than one reason.
[5] Percentage of participants not eligible.

Source: SCHARP (Gayathri) - /trials/mtn/p030/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_main_site.sas, SAS Version 9.4 (02DEC2025,6:25)

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Last pregnancy outcome less than 90 days prior to Enrollemnt	0 (0%)	0 (0%)	0 (0%)
Gynecologic or genital procedure 60 days or less prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Currently breastfeeding or planning to breastfeed during the course of the study	0 (0%)	0 (0%)	0 (0%)
Participant in any other research study involving drugs,medical devices,vaginal products,or vaccines in the 60 days prior to enrollment	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher AST or ALT at Screening visit	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher Creatinine at Screening visit	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher hemoglobin at Screening visit	1 (9%)	1 (17%)	0 (0%)
Has any other condition that,in the opinion of the IoR/ designee,would preclude informed consent	3 (27%)	1 (17%)	2 (40%)
Current use or planned use of antibiotics and/or corticosteroids that interact with levonorgestrel	0 (0%)	0 (0%)	0 (0%)
Ineligible due to inclusion[5]	4 (36%)	2 (29%)	2 (50%)
Age 18 through 45 (inclusive) at Screening	0 (0%)	0 (0%)	0 (0%)
Able and willing to provide written informed consent	1 (9%)	1 (17%)	0 (0%)
Able and willing to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)
Able to communicate in spoken and written English	0 (0%)	0 (0%)	0 (0%)
Available for all visits and able and willing to comply with all study procedural requirements, including SMS requirements	1 (9%)	0 (0%)	1 (20%)
Willing to abstain from receptive intercourse for 24 hours preceding the Enrollment Visit and for the duration of study participation	0 (0%)	0 (0%)	0 (0%)
Per participant report, using an effective non-hormonal method of contraception at Enrollment, and intending to continue the use of an effective, non-hormonal method for the duration of study participation	1 (9%)	0 (0%)	1 (20%)
In general good health as determined by the IOR/ designee at Screening and Enrollment	1 (9%)	0 (0%)	1 (20%)
HIV uninfected based on testing performed at Screening and Enrollment	0 (0%)	0 (0%)	0 (0%)
Regular menstrual cycles of approximately 21 to 35 days duration	0 (0%)	0 (0%)	0 (0%)

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Intact uterus with at least one ovary	0 (0%)	0 (0%)	0 (0%)
Per participant report as Screening and Enrollment, states a willingness to refrain from inserting any non-study vaginal products or objects into the vagina for 24 hours prior to enrollment and for the duration of study participation	0 (0%)	0 (0%)	0 (0%)
Women over the age of 21 (inclusive) must have documentation of satisfactory Pap within the past 3 years prior to Enrollment consistent with Grade 0 or satisfactory evaluation with no treatment required of Grade 1 or higher Pap result	1 (9%)	1 (17%)	0 (0%)
At Screening and Enrollment, agrees not to participate in other research studies involving drugs, medical devised, vaginal products, or vaccines after the Screening Visit and for the duration of study participation	0 (0%)	0 (0%)	0 (0%)

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