MTN 037 - A Phase 1 Safety and Pharmacokinetic Study of PC-1005 (MIV-150/Zinc Acetate/Carrageenan Gel) Administered Rectally to HIV-1 Seronegative Adults
Data as of December 5, 2022

Screen-out Summary by Site

	Pittsburgh	Birmingham	All Sites
Participants Screened[1]	7	9	16
Participants Enrolled[2, 3]	6 (86%)	7 (78%)	13 (81%)
Participants not Enrolled	1 (14%)	2 (22%)	3 (19%)
Participant did not complete all screening procedures[4]	0 (0%)	1 (50%)	1 (33%)
Participant is eligible but did not enroll	0 (0%)	0 (0%)	0 (0%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[5]	1 (100%)	1 (50%)	2 (67%)
Not men or women who are 18 years or older at Screening	0 (0%)	0 (0%)	0 (0%)
Not able and/or willing to provide written informed consent	0 (0%)	0 (0%)	0 (0%)
HIV-1/2 infected at Screening and Enrollment and/or not willing to receive HIV test results	0 (0%)	0 (0%)	0 (0%)
Not able and/or willing to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)
Not available to return for all study visits and/or not willing to comply with study requirements	0 (0%)	1 (100%)	1 (50%)
Not in general good health at Screening and/or Enrollment	0 (0%)	0 (0%)	0 (0%)
At Screening, no history of consensual RAI at least once in their lifetime per participant report	0 (0%)	0 (0%)	0 (0%)
Not willing to not take part in other research studies for the duration of the study participation	0 (0%)	0 (0%)	0 (0%)
Not willing to follw abstinence requirements for the duration of the study participation	0 (0%)	0 (0%)	0 (0%)
For participants of childbearing potential: a non negative pregnancy test at Screening and Enrollment	0 (0%)	0 (0%)	0 (0%)
For participants of childbearing potential: not using and/or intending to continue use of an effective method of contraception	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher Hemoglobin at Screening	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher Platelet count at Screening	0 (0%)	0 (0%)	0 (0%)
Grade 2 or higher White blood count at Screening	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher Aspartate aminotransferase (AST) or Alanine transaminase (ALT) at Screening	0 (0%)	0 (0%)	0 (0%)
Serum creatinine > 1.3x site ULN	0 (0%)	0 (0%)	0 (0%)
INR > 1.5x site ULN	0 (0%)	0 (0%)	0 (0%)
History of inflammatory bowel disease per participant report	0 (0%)	0 (0%)	0 (0%)
Known adverse reaction to latex or polyurethane (ever)	0 (0%)	0 (0%)	0 (0%)
Anticipated use of and/or unwillingness to abstain from Anticoagulant medications during study participation	0 (0%)	0 (0%)	0 (0%)
Anticipated use of and/or unwillingness to abstain from Rectally-admin istered medications during study participation	0 (0%)	0 (0%)	0 (0%)
Known adverse reaction to any of the components of the study product	0 (0%)	0 (0%)	0 (0%)
Use of PrEP for HIV prevention within 1 month prior to Enrollment, or anticipated use or unwillingness to abstain from PrEP	0 (0%)	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 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 (hhx) - /trials/mtn/p037/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_site.sas, SAS Version 9.4 (06DEC2022,5:32)

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Use of PEP for potential HIV exposure within the 3 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Condomless RAI or penile-vaginal intercourse with a partner known or unsure to be HIV-positive in 6 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Non-therapeutic injection drug use in the 12 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
Participation in research studies involving products such as drugs, medical devices or vaccines within 30 days of Enrollment	0 (0%)	0 (0%)	0 (0%)
Gynecologic, genital, or rectal procedure 60 days or less prior to Enrollment, or rectal biopsy, 7 days or less prior to Enrollment	0 (0%)	0 (0%)	0 (0%)
At Screening or Enrollment, per participant records, diagnosis or treatment of any anogenital STI within past 3 months	0 (0%)	0 (0%)	0 (0%)
At screening or enrollment, active pharyngeal, anorectal infection or RTI requiring treatment per current CDC guidelines	1 (100%)	0 (0%)	1 (50%)
At Screening or Enrollment, current symptomatic UTI	0 (0%)	0 (0%)	0 (0%)
Pregnant or breastfeeding at either Screening or Enrollment or intends to become pregnant or start breastfeeding	0 (0%)	0 (0%)	0 (0%)
Last pregnancy outcome 90 days or less prior to Screening	0 (0%)	0 (0%)	0 (0%)
Has a condition that, per IoR/designee, would preclude informed consent, make study unsafe, complicate interpretation	0 (0%)	0 (0%)	0 (0%)

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