Evaluation of Doravirine/Lamivudine/Tenofovir Disoproxil Fumarate for Non-occupational Post Exposure Prophylaxis, a Prospective Open-Label Study (DORAVIPEP)

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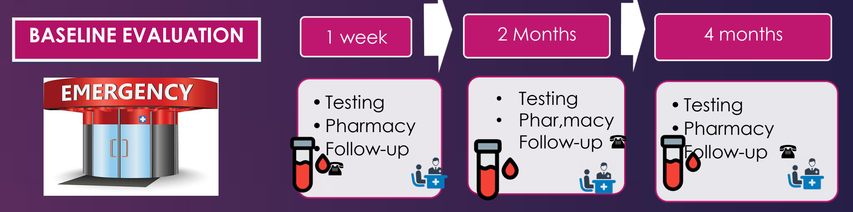
Background: Most guidelines still recommend multiple pill regimens for post-exposure prophylaxis (PEP), and completion rates for PEP are often low. Few studies assess safety, tolerability, and adherence to new single table regimens (STR). We evaluated the combination of Doravirine/Lamivudine/Tenofovir as STR for non-occupational PEP.

Methods and materials: This is a prospective, open-label, single-arm study. Individuals attending the emergency room due to potential sexual exposure to HIV and who met the criteria for PEP received Doravirine/Lamivudine/Tenofovir. The primary endpoint was PEP non-completion on day 28, and the secondary endpoints were adverse effects, adherence, and rate of seroconversions. Follow-up consultations were appointed on days 10, 60, and 120. Clinical trials.gov number: NCT04233372.

DATA COLLECTION — REDCap

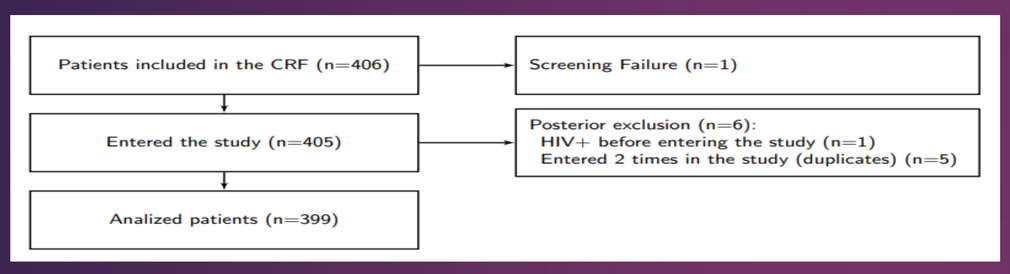
ANALYSIS — STATA



	Day 0	Week 4-8 (2M)	Week 16 (4M)
Clinical evaluation	□	□	□
Biochemistry, liver and pancreatic profile and CBC	□	□	□
HIV, HBV, HCV, HCA and syphilis serology (**)	□	□	□
cholesterol, HDL, LDL , triglycerides	□	□	□
Syphilis serology, tetanus vaccination, antibiotic prophylaxis	□		□
Questionnaire on adherence to ART*** and pill count		□	
Adverse events	□	□	□

(**) Syphilis serology will only be made for sexual exposures until week 12 (&) In special cases according to medical opinion (e.g., sexual assault).
(***)SMAQ questionnaire

Study Flow-Chart

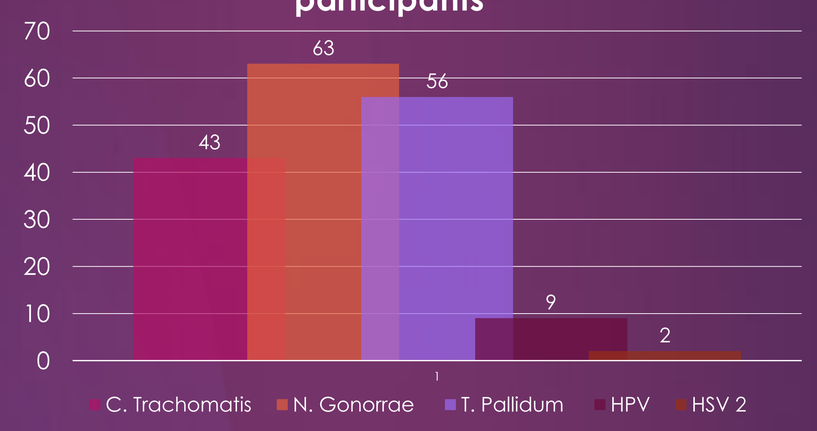


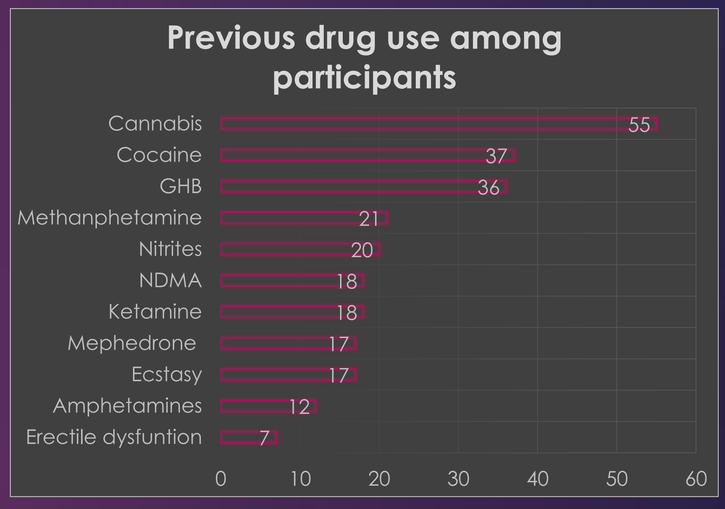
Results: From 01-09-2020 to 14-03-2022, 399 individuals were enrolled in the study. The median age was 30 (27-36) years, and 91% (n=365) were males. The mode of exposure was HSH in 84% (n=331) and risk assessment as ascertained by the treating provider, was high in 97% (n=385) of the cases. PEP users selfreferred use of recreational drugs in 30% (n=109) of cases.

Demographic characteristics of the DORAVIPEP cohort

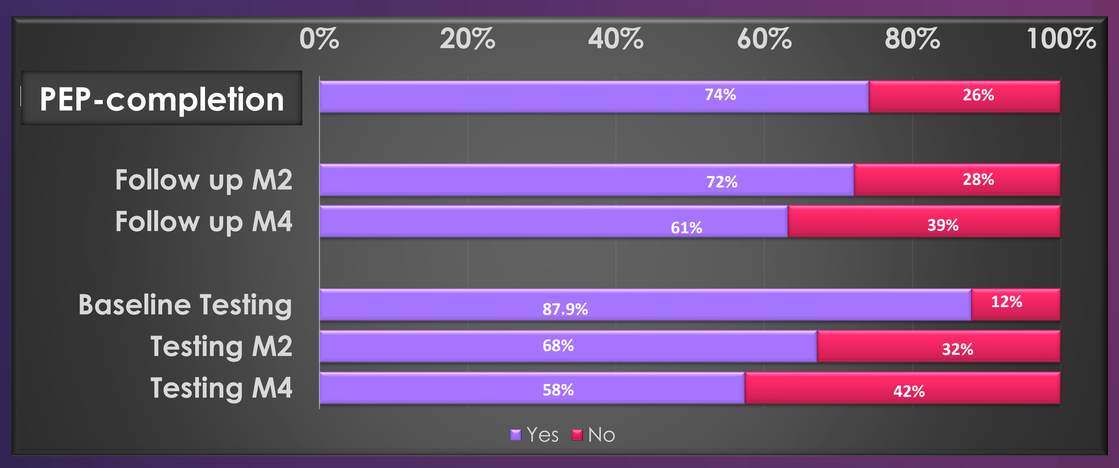
Variable	Stratification	Outcome
Risk assessment (2) [1]	Low-Intermediate	12 (3%)
	High	385 (97%)
Age (in years) [2]		30 (27 ; 36) [399]
Sex (at birth) [1]	female	31 (8%)
	male	365 (91%)
	non binary	3 (1%)
Sex (at birth) (2) [1]	Female	31 (8%)
	Male	368 (92%)
Sexual orientation [1]	Heterosexual	53 (13%)
	Homosexual	331 (84%)
	Transexual	11 (3%)
Homosexual [1]	No	53 (13%)
	Yes	342 (87%)
European origin [1]	No	151 (40%)
	Yes	231 (60%)
STI previous to inclusion [1]	No	265 (68%)
	Yes	124 (32%)
Is there any prophylaxis to report? [1]	No	182 (46%)
	Yes	217 (54%)

1: n (Column percentage)
2: Median (IQR) [n]



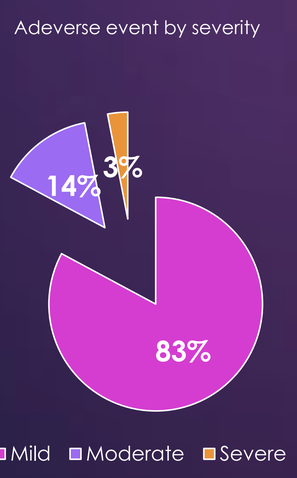


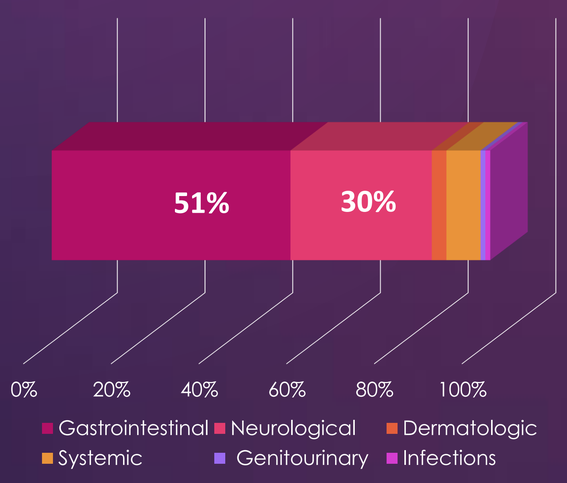
Primary endpoint PEP non-completion. Follow-up rates and follow-up

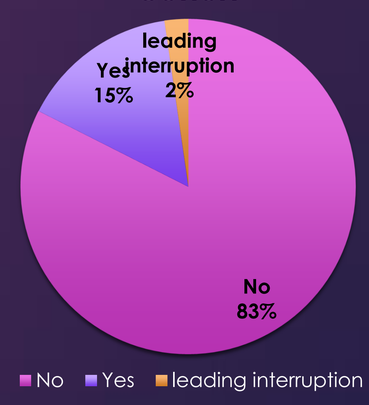


PEP non-completion at day 28 was 26% (n=103) (95%CI: 22%; 30%), reasons for non-completion were: Loss to follow-up 92 (89%), Intolerance 9(9%) and Patients Decision/Withdrawal Consent 2 (2%). In the multivariate regression model, older age for a patient makes it less likely for him to discontinue the treatment prematurely 0.95 (0.92;0.98) p=0.0016.

Adverse events were reported by 70(18%) patients during the treatment period. Gastrointestinal symptoms were the most common, 51% (n=49), followed by neurological, 30% (n=29). There were no potentially life-threatening (grade IV) adverse events. Most of the adverse events were mild and self-limiting, 83% (n=82). Adherence to PEP in the assessed users was 96%(337/351) and 99%(285/289) by self-report and pill count data at day ten and week 4, respectively. There were no cases of HIV transmission in this cohort.







Conclusions: Doravirine/Lamivudine/Tenofovir is a well-tolerated option for once-daily PEP that compares favourably with other recommended PEP regimens

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