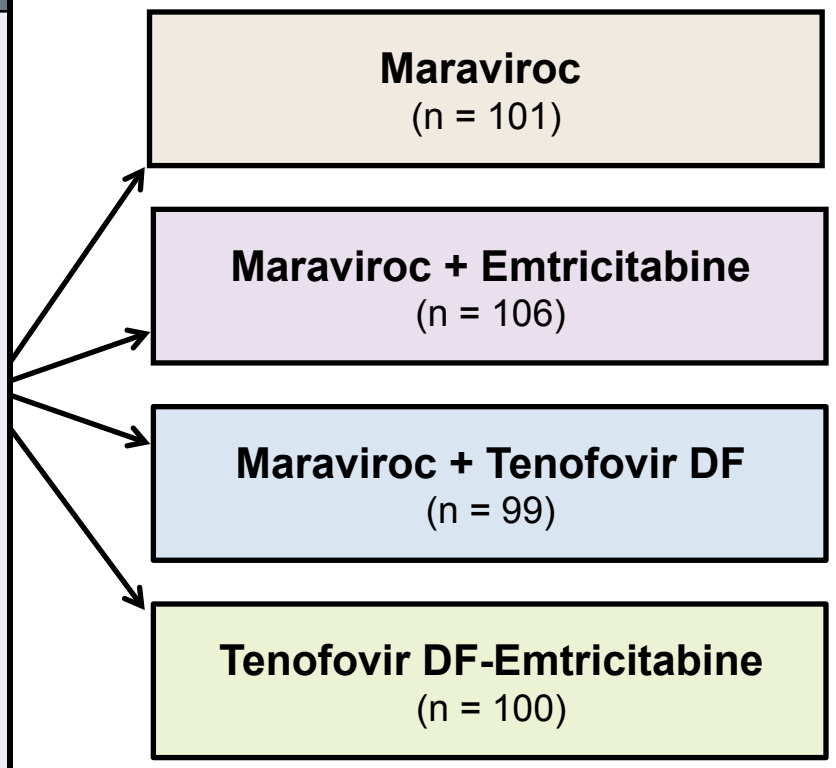
Maraviroc +/- FTC or TDF for Preexposure Prophylaxis

HPTN 069/ACTG 5305

Maraviroc +/- FTC or TDF for Preexposure Prophylaxis
HPTN 069/ACTG 5305: Study Design

Study Design: HPTN 069/ACTG 5305

- **Background**: Phase 2b, randomized, double-blind study of the safety and tolerability of maraviroc (alone or combined with FTC or TDF) for preexposure prophylaxis (PrEP), as compared to TDF-FTC, for at-risk men and transgender women
- **Inclusion Criteria (n = 406)**
  - Men and transgender women who have sex with men who self-reported condomless anal sex with at least one man within last 90 days
  - Creatinine clearance ≥70 mL/min
  - Negative HIV Ag/Ab and RNA
  - Negative hepatitis B surface Ag
  - No reported injection-drug use



Source: Gulick RM et al. J Infect Dis. 2017;215(2):238-246.

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HPTN 069/ACTG 5305: Results

HPTN 069/ACTG 5305: Adverse Events (AE's) at Week 48 ITT Analysis				
	MVC (n = 101)	**MVC + FTC** (n = 106)	**MVC + TDF** (n = 99)	**TDF-FTC** (n = 100)
Permanent study drug discontinuation	7 (7%)	9 (9%)	12 (12%)	8 (8%)
Time to permanent discontinuation, median days (IQR)	120 (74-263)	66 (42-222)	113 (42-260)	67 (34-141)
Grade 3-4 AE's, # of participants, # of events	13, 15	11, 15	11, 14	20, 23
Grade 3-4 AE's, adverse event rate per person-year	0.17	0.16	0.17	0.19

Number discontinuing and time to discontinuation did not differ among study regimens (P = .60).
Rates of grade 3–4 adverse events did not differ among regimens (P = .37).

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HPTN 069/ACTG 5305: Results

Week 48 Results (Intention to Treat Analysis, ITT)

HIV Infections that Occurred During the HPTN 069/ACTG 5305 study

	Age	HIV Risk Group	Study Arm	1st Reactive HIV Test, Study Week	HIV RNA, copies/mL	HIV Tropism	Genotypic Drug Resistance	Study drug concentration at seroconverstion visit, ng/mL
1	20	MSM	MVC + TDF	9	122,150	R5	None	MVC: 0 TFV: 0
2	61	MSM	MVC	16	981	R5	None	MVC: 145
3	21	MSM	MVC	28	106,240	R5	None	MVC: 0
4	35	MSM	MVC	38	13,626	R5	None	MVC: 6.7
5	36	MSM	MVC	48	52,191	R5	None	MVC: 0.7

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Maraviroc +/- FTC or TDF for Preexposure Prophylaxis
HPTN 069/ACTG 5305: Conclusions

Conclusions: "MVC-containing regimens were safe and well tolerated compared with TDF + FTC; this study was not powered for efficacy. Among those acquiring HIV infection, drug concentrations were absent, low, or variable. MVC-containing regimens may warrant further study for pre-exposure prophylaxis.."

Source: Gulick RM et al. J Infect Dis. 2017;215(2):238-246.

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

National HIV Curriculum

AETC AIDS Education & Training Center Program
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