VISUAL ABSTRACTS

HIV PrEP Studies

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ABOUT THIS INFORMATION GUIDE

This visual abstract study series is intended for health care professionals involved in care of persons who may benefit from receiving HIV preexposure prophylaxis (PrEP). These visual abstracts provide relevant information pertaining to major HIV PrEP studies. This guide has been created and produced by the University of Washington Infectious Diseases Education & Assessment Program (IDEA) as part of the federally-funded *National HIV PrEP Curriculum* project.

PERMISSION TO USE THIS GUIDE

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ATN 110

HIV PrEP for Young MSM

Summary

HIV PrEP was overall acceptable and safe among young men who have sex with men (YMSM), though adherence and follow-up were imperfect and decreased over time

Study Design

Open-label, demonstration project and phase II safety study

Participants

200
HIV-seronegative YMSM

18 - 22
Years of age

≈ 50% Black youth
≈ 25% Hispanic youth

Interventions

1. All participants were offered tenofovir DF-emtricitabine (TDF-FTC) 1 pill daily
2. Monthly study visits through week 12, then quarterly visits through week 48
3. Counseling, condoms, and STI screening at each visit
4. Adherence estimated using dried blood spot tenofovir diphosphate (TFV-DP) levels

Results

Acceptability	60% reported taking the TDF-FTC pill every day to be acceptable
Adherence	56% had TFV-DP levels suggesting ≥4 pills/week at week 4; major drop in adherence observed at week 24 and decreased to 34% by week 48
Behavior	High sexual activity and frequent bacterial STI diagnoses at baseline but stable throughout the study
Efficacy	4 HIV seroconversions (incidence 3.29/100 person-years of follow up)

Source: Hosek SG, Rudy B, Landovitz R, et al. J Acquir Immune Defic Syndr. 2017;74:21-9. [PMID: 27632233]

ATN 113

HIV PrEP for Adolescent MSM

Summary

HIV PrEP was overall acceptable and safe among adolescent men who have sex with men (MSM), though adherence and follow-up decreased over time

Study Design

Phase II, open-label, demonstration project in multiple U.S. cities

Participants

78 HIV-seronegative MSM

15 - 17 Years of age

29% Black youth

21% Hispanic youth

Interventions

1. All participants were offered tenofovir DF-emtricitabine (TDF-FTC) 1 pill daily
2. Monthly study visits for 12 weeks, then quarterly visits through 48 weeks
3. Counseling, condoms, and STI screening at each visit
4. Adherence estimated using dried blood spot tenofovir diphosphate (TFV-DP) levels

Results

Acceptability	High acceptability – 64% participants completed 48 weeks of follow up
Adherence	54% with TFV-DP levels suggesting ≥4 pills/week at week 4, decreased to 22% at week 48 (striking decrease after follow-up visits moved to quarterly)
Behavior	Number of sex partners and sex acts did not change significantly over time; there was a trend towards fewer bacterial STIs later in the study
Efficacy	3 HIV seroconversions (incidence 6.4/100 person-years of follow up)
Safety	Overall well tolerated; bone mineral density z scores at the hip and spine did not change significantly; total body z score decreased

Source: Hosek SG, Landovitz RJ, Kapogiannis B, et al. JAMA Pediatr. 2017;171:1063-71. [PMID: 28873128]

BANGKOK TDF

HIV PrEP for Persons who Inject Drugs

Summary

Daily oral tenofovir DF (TDF) reduced the risk of HIV infection for persons who inject drugs

Study Design

Randomized, phase 3, double-blind, placebo-controlled trial conducted in Bangkok, Thailand

Participants

2,413
HIV-seronegative adults

20 - 60
Years of age

Used injection drugs during prior year

- Not pregnant
- Not breastfeeding
- No hepatitis B

Interventions

Placebo	TDF
One tablet daily	One tablet daily
n = 1,209	n = 1,204

All participants received risk-reduction counseling, bleach, and condoms.

Results

	Placebo	TDF
New HIV Infections	33	17
Incident HIV Infection (per 100 person-years)	0.68	0.35
HIV Risk Reduction	49% reduction in HIV incidence with oral TDF compared to placebo (95% CI 9.6 to 72.2; p=0.01)	

Source: Choopanya K, Martin M, Suntharasamai P, et al. Lancet. 2013;381:2083-90. [PMID: 23769234]

DISCOVER TRIAL

TDF-FTC versus TAF-FTC for HIV Prevention

Summary

Daily tenofovir alafenamide-emtricitabine (TAF-FTC) is non-inferior to tenofovir DF-emtricitabine (TDF-FTC) for HIV prevention; TAF-FTC had more favorable effects on bone mineral density and renal function

Study Design

Randomized, double-blind, multicenter, active-controlled, phase 3, noninferiority trial

Participants

Overall	Key Population
5,387 HIV-seronegative adults	5,313 Men who have Sex with Men

Interventions

TDF-FTC one tablet daily (Tenofovir DF-emtricitabine)	TAF-FTC one tablet daily (Tenofovir alafenamide-emtricitabine)
n = 2,693	n = 2,694

Results

	TDF-FTC one tablet daily (Tenofovir DF-emtricitabine)	TAF-FTC one tablet daily (Tenofovir alafenamide-emtricitabine)
Incident HIV Infection (per 100 person-years)	0.34 (95% CI 0.19 to 0.56)	0.16 (95% CI 0.06 to 0.33)
Hip Bone Mineral Density (median change from baseline)	-0.99%	0.18%
Serum Creatinine (median change from baseline)	-0.88 µmol/L	0.88 µmol/L

Source: Mayer KH, Molina JM, Thompson MA, et al. Lancet. 2020;396:239-54. [PMID: 32711800]

HPTN 083

Cabotegravir for HIV Prevention in Men who have Sex with Men

Summary

Long-acting injectable cabotegravir (CAB-LA) was superior to daily oral tenofovir DF-emtricitabine (TDF–FTC) in preventing HIV infection in HIV-seronegative adults, primarily men who have sex with men (MSM).

Study Design

Randomized, double-blind, double-dummy, noninferiority trial

Participants

Overall	Key Population
4,566 HIV-seronegative adults	3,992 Men who have Sex with Men

Interventions

Cabotegravir	TDF-FTC
Oral cabotegravir lead-in followed by CAB-LA	Daily oral tenofovir DF-emtricitabine
n = 2,282	n = 2,284

Results

	Cabotegravir	TDF-FTC
New HIV Infections	13	39
Incident HIV Infection (per 100 person-years)	0.41	1.22

Results were readjudicated, demonstrating 58 observed infections overall: 16 with CAB and 42 with TDF-FTC, resulting in HIV incidence of 0.37 in CAB group (95% CI 0.19 to 0.65)

Source: Landovitz RJ, Donnell D, Clement ME, et al. N Engl J Med. 2021;385:595-608. [PMID: 34379922]

HPTN 084

Cabotegravir for HIV Prevention in Women

Summary

Long-acting injectable cabotegravir (CAB-LA) was superior to daily oral tenofovir DF-emtricitabine (TDF-FTC) for preventing HIV infection among women

Study Design

Randomized, double-blind, double-dummy, superiority trial

Participants

3,224 HIV-seronegative women

18 - 45 Years of age

20 Sites in Sub-Saharan Africa

Interventions

Cabotegravir
Oral cabotegravir lead-in followed by CAB-LA
n = 1,614

TDF-FTC
Daily oral tenofovir DF-emtricitabine
n = 1,610

Results

	Cabotegravir	TDF-FTC
New HIV Infections	4	36
Incident HIV Infection (per 100 person-years)	0.20 (95% CI 0.06-0.52)	1.85 (95% CI 1.3-2.57)
HIV Risk Reduction	88% lower risk of new HIV infections in CAB-LA arm; superiority of CAB-LA driven by adherence advantage over TDF-FTC	

Source: Delany-Moretlwe S, Hughes JP, Bock P, et al. Lancet. 2022;399:1779–89. [PMID: 35378077]

IPERGAY

On-Demand TDF-FTC as HIV PrEP for MSM

Summary

On-demand (2-1-1) tenofovir DF-emtricitabine (TDF-FTC) was highly effective at preventing HIV infection for MSM

Study Design

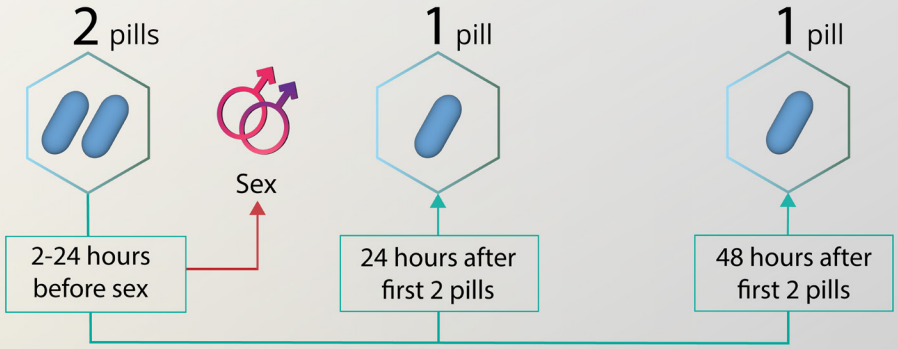
Randomized, phase 3, double-blind, placebo-controlled trial conducted in France and Canada

Participants

400
Adult HIV-seronegative MSM

- Condomless rectal sex in prior 6 months
- No hepatitis B
- Normal renal function

On-demand (2-1-1) TDF-FTC Dosing Example



Interventions

Placebo
On-demand (2-1-1) dosing
n = 201

TDF-FTC
On-demand (2-1-1) dosing
n = 199

Results

	Placebo	TDF-FTC
New HIV Infections	14	2
Incident HIV Infections (per 100 person-years)	6.60	0.91
HIV Risk Reduction	86% relative risk reduction in HIV incidence (95% CI 40 to 98; p=0.002)	

Source: Molina JM, Capitant C, Spire B, et al. N Engl J Med. 2015;373:2237-46. [PMID: 26624850]

IPREX

HIV PrEP with TDF-FTC for Men who have Sex with Men

Summary

Daily oral tenofovir DF-emtricitabine (TDF-FTC) significantly reduced the risk for new HIV infections compared to placebo

Study Design

Multinational, randomized, double-blind, placebo-controlled trial

Participants

Overall	Key Population
2,499 HIV-seronegative adults	2,470 Men who have Sex with Men

Study Participant Characteristics
- Age ≥18 years
- High risk for HIV acquisition

Interventions

Placebo	TDF-FTC
One tablet daily	One tablet daily
n = 1,248	n = 1,251

Results

	Placebo	TDF-FTC
New HIV Infections	64	36
HIV Risk Reduction	44% reduction in incidence of HIV infection (95% CI 15 to 63; p<0.001)	
	92% reduction for those with detectable study-drug level	

Source: Grant RM, Lama JR, Anderson PL, et al. N Engl J Med. 2010;363:2587-99. [PMID: 21091279]

PARTNERS PREP

HIV PrEP Among Heterosexual HIV Serodifferent Couples

Summary

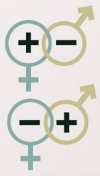
HIV PrEP with daily, oral tenofovir DF-emtricitabine (TDF-FTC) or tenofovir DF (TDF) was highly effective at preventing HIV transmission among heterosexual HIV serodifferent couples

Study Design

Randomized, double-blind, placebo-controlled, 3-arm trial performed in Kenya and Uganda

Participants

4,747
Heterosexual HIV-serodifferent couples



Serodifferent: One partner is HIV-seropositive and the other is HIV seronegative

The HIV-seropositive partner was not taking antiretroviral therapy

Interventions

Placebo	TDF	TDF-FTC
One tablet daily	One tablet daily	One tablet daily
n = 1,584	n = 1,584	n = 1,579

Results

	Placebo	TDF	TDF-FTC
New HIV Infections	52	17	13
HIV Risk Reduction	Not applicable	67% reduction in HIV incidence compared to placebo (95% CI 44 to 81; P<0.001)	75% reduction in HIV incidence compared to placebo (95% CI 55 to 87; P<0.001)

Source: Baeten JM, Donnell D, Ndase P, et al. N Engl J Med. 2012;367:399-410. [PMID: 22784037]

PREVENIR

On-Demand TDF-FTC vs. Daily TDF-FTC for HIV PrEP

Summary

On-demand (2-1-1) and daily dosing of tenofovir DF-emtricitabine (TDF-FTC) were equally effective at preventing HIV acquisition in a trial of mainly men who have sex with men (MSM)

Study Design

Prospective, obervational cohort study conducted at 26 sites in the Paris region of France (participants could choose daily vs. on-demand dosing).

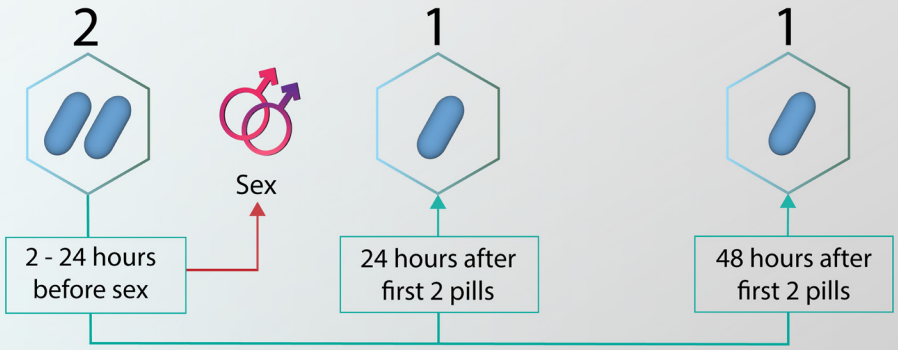
Participants

3,056
Adults

98.7% MSM

44.0% HIV PrEP naive

On-demand (2-1-1) Dosing Example



Interventions

TDF-FTC
Daily
n = 1,540

TDF-FTC
On-demand (2-1-1) dosing
n = 1,509

Results

New HIV Infections	3	3
Incident HIV Infections (per 100 person-years)	0.195	0.199
HIV Risk Reduction	No statistically significant difference (95% CI 0.13 to 7.49; p=0.99)	

Source: Molina JM, Ghosn J, Assoumou L, et al. Lancet HIV. 2022;9:e554-e562. [PMID: 35772417]

PROUD

Immediate vs. Delayed HIV PrEP for MSM at High Risk for HIV

Summary

HIV PrEP with daily, oral tenofovir DF-emtricitabine (TDF-FTC) was highly effective at preventing HIV for men who have sex with men (MSM) and are at high risk for HIV acquisition

Study Design

Randomized, open-label, phase 4 study conducted in England

Participants

544
HIV-seronegative MSM

Reported condomless anal sex during the 90 days prior to enrollment

Interventions

Defer PrEP for 1 year	Immediate PrEP
Then daily, oral TDF-FTC	Daily, oral TDF-FTC
n = 269	n = 275

Results

	Defer PrEP for 1 year	Immediate PrEP
New HIV Infections	20	3
Incident HIV Infections (per 100 person-years)	9.0	1.2
HIV Risk Reduction	86% relative reduction in HIV incidence with immediate TDF-FTC (90% CI 64 to 96; p=0.0001) Trial unblinded early and all participants offered HIV PrEP due to high efficacy	

Source: McCormack S, Dunn DT, Desai M, et al. Lancet. 2016;387:53-60. [PMID: 26364263]

TDF2

Daily TDF-FTC as HIV PrEP for Heterosexual Men and Women

Summary

Daily, oral tenofovir DF-emtricitabine (TDF-FTC) was highly effective at preventing HIV infection for heterosexual men and women at risk for HIV acquisition

Study Design

Phase 3, randomized, double-blind, placebo-controlled trial conducted in Botswana

Participants

1,219
HIV-seronegative adults

52.5% sexually active adult men

45.7% sexually active adult women

18 - 39
Years of age

Interventions

Placebo	TDF-FTC
One tablet daily	One tablet daily
n = 608	n = 611

Results

	Placebo	TDF-FTC
New HIV Infections	24	9
Incident HIV Infection (per 100 person-years)	3.1	1.2
HIV Risk Reduction	62.2% relative risk reduction with TDF-FTC (95% CI 21.5 to 83.4; p=0.03)	

Source: Thigpen MC, Kebaabetswe PM, Paxton LA, et al. N Engl J Med. 2012;367:423-34. [PMID: 22784038]

PURPOSE 1

Twice-Yearly Lenacapavir Versus TAF/FTC or TDF/FTC for HIV Prevention for Women

Summary

Lenacapavir demonstrated remarkable effectivess at preventing HIV in women; zero HIV infections occurred in trial participants receiving twice-yearly injectable lenacapavir.

Study Design

Phase 3, double-blind, randomized controlled trial conducted at sites in South Africa and Uganda

Participants

- 5,338 Adolescent girls and young women
- 16 - 25 Years of age
- Sexually active with male partners
- Not using PrEP at enrollment
- Unknown HIV status and no HIV testing within prior 3 months

Interventions

Lenacapavir	TAF-FTC	TDF-FTC
Two 1.5 mL SQ injections every 26 weeks with a daily oral placebo	One tablet daily with placebo injections every 26 weeks	One tablet daily with placebo injections every 26 weeks
n = 2,134	n = 2,136	n = 1,068

Results

	Lenacapavir	TAF-FTC	TDF-FTC
New HIV Infections	0	39	16
HIV Incidence (per 100 person-years)	0 (95% CI 0.00 to 0.19)	2.02 (95% CI 1.44 to 2.76)	1.69 (95% CI 0.96 to 2.74)

Background Incidence

Estimated background HIV incidence in 8,094 participants screened for the study: 2.41 per 100 person-years (95% CI 1.82 to 3.19)

Notes

- Adherence with TAF/FTC and TDF/FTC was low
- Injection site reactions were common with lenacapavir but very few participants discontinued

Abbreviations
SQ = subcutaneous
TAF-FTC = tenofovir alafenamide-emtricitabine
TDF-FTC = tenofovir DF-emtricitabine

Source: Bekker LG, Das M, Karim QA, et al. N Engl J Med. 2024;391:1179-92. [PMID: 39046157]

PURPOSE 2

Twice-Yearly Lenacapavir or Daily TDF/FTC for HIV Prevention for Men who Have Sex with Men (and Other Populations*)

Summary

The incidence of HIV with twice-yearly injectable lenacapavir was significantly lower than the incidence with daily oral TDF/FTC and lower than the estimated background incidence, showing high efficacy for HIV prevention for men who have sex with men and other populations.*

Study Design

Phase 3, multinational, double-blind, randomized controlled trial conducted at 92 sites in geographic areas with evidence of substantial ongoing HIV transmission

Participants

3,265
Participants

- Condomless receptive anal sex with male partners
- Not using PrEP in prior 3 months
- Participants at least 16 years of age
- Unknown HIV status and no HIV testing in prior 3 months

Interventions

2:1 Randomization

Lenacapavir
Two 1.5 mL SQ injections every 26 weeks with a daily oral placebo
n = 2,179

TDF-FTC
One tablet daily with placebo injections every 26 weeks
n = 1,086

Results

	Lenacapavir	TDF-FTC
New HIV Infections	2	9
HIV Incidence (per 100 person-years)	0.1 (95% CI 0.01 to 0.37)	0.93 (95% CI 0.43 to 0.77)
Background Incidence	Estimated background incidence of HIV in the screened population (4,634 participants) was 2.37 per 100 person-years (95% CI 1.65 to 3.42)	
Notes	• No safety concerns identified • Very few discontinuations on lenacapavir	

***See original publication for details of all populations included in study**

Abbreviations
TDF-FTC = Tenofovir DF-emtricitabine
SQ = Subcutaneous

Source: Kelley CF, Acevedo-Quiñones M, Agwu AL, et al. N Engl J Med. 2025;392:1261-76. [PMID: 39602624]

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