AVAC
Global Advocacy for HIV Prevention

The Years Ahead in Biomedical HIV Prevention Research

Status of select biomedical HIV prevention clinical trials

Efficacy Trial

2019 | 2020 | 2021 | 2022 | 2023 | 2024

Vaginal Ring

Dapivirine Ring (Monthly)

Jul 2020: European Medicines Agency issues a positive opinion

Jan 2021: WHO recommends as an additional prevention choice for women at substantial risk of HIV. Approved in four African countries and under review by a number of additional regulatory authorities.

Oral PrEP

F/TAF (Daily pill)

DISCOVER

Oct 2019: FDA approves F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex

PURPOSE 1

Trial of six-monthly injectable lenacapavir planned in 5,010 AGYW in South Africa, Uganda alongside daily oral F/TAF.

Islatravir (Monthly pill)

IMPOWER-22

Randomized controlled trial of monthly islatravir; ongoing in 4,500 women in the US

On hold. Related islatravir studies showed lower lymphocyte and CD4+ T cell counts in some participants.

IMPOWER-24

Randomized controlled trial of monthly islatravir in men and trangender women who have sex with men across the world

On hold. Related islatravir studies showed lower lymphocyte and CD4+ T cell counts in some participants.

Long-Acting Injectable

Cabotegravir (Every two months)

HPTN 083

Randomized controlled trial of injectable cabotegravir every two months; ongoing in 4,500 MSM and transgender women in Argentina, Brazil, Peru, South Africa, Thailand, US, Vietnam

Dec 2021: FDA approves CAB-LA for PrEP in the US. Multiple applications under review with other regulatory bodies.

HPTN 084

Randomized controlled trial of injectable cabotegravir every two months; ongoing in 3,200 women in Botswana, Kenya, Malawi, South Africa, Uganda, Zimbabwe

Lenacapavir (Every six months)

PURPOSE 1

Trial of six-monthly injectable lenacapavir planned in 5,010 AGYW in South Africa, Uganda alongside daily oral F/TAF.

PURPOSE 2

Trial of six-monthly injectable lenacapavir in 3,000 cisgender MSM, transgender women, transgender men, and gender non-binary individuals.

Preventive HIV Vaccine

ALVAC/gp120 w/MF59

HVTN 702

February 2020: Trial stopped early for non-efficacy.

Randomized controlled trial of ALVAC/gp120 prime-boost with MF59 adjuvant, six doses over 18 months; 5,400 men and women in South Africa; immunizations halted for non-efficacy; follow-up ongoing

Ad26/gp140 boost

Imbokodo (HVTN 705/ HPX2008)

August 2021: The vaccine was safe, but did not significantly reduce the risk of HIV.

Randomized controlled trial of Ad26 prime with gp140 boost; four doses over 12 months; fully enrolled 2,600 women in Malawi, Mozambique, South Africa, Zambia, Zimbabwe

Ad26/clade C gp140 & mosaic gp140 boost

Mosaico (HVTN 706/ HPX3002)

Randomized controlled trial of Ad26 prime with clade C and mosaic gp140 boost; ongoing in 3,800 MSM and transgender people in Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain, US

Oral PrEP and vaccine

PrEPVacc

Randomized controlled trial of DNA-MVA-env or DNA-env with F/TAF or F/TDF; planned in 1668 participants in Mozambique, South Africa, Tanzania, Uganda

Antibody

VRC01

AMP (HVTN 704/ HPTN 085)

Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 2,700 MSM and transgender men & women in Brazil, Peru, Switzerland, US

Jan 2021: VRC01 did not significantly reduce the overall risk of HIV acquisition, but it reduced risk from HIV strains classified as highly-sensitive to VRC01.

AMP (HVTN 703/ HPTN 081)

Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 1,900 women in Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe

Ongoing ////// Planned

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