Adherence to HIV vaccine dose schedule and associated factors among adults enrolled in a HIV vaccine trial in Uganda

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Background

- Ensuring the completion of multiple-dose vaccine schedules is vital for establishing a protective immune response.
- We examined adherence to the vaccine schedule and associated factors within an HIV vaccine trial conducted in Uganda.

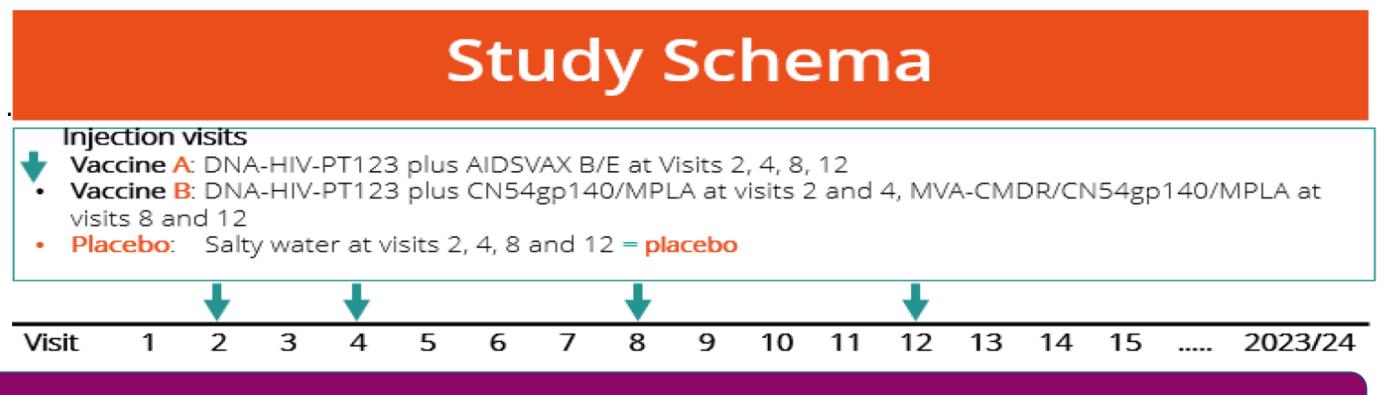
Methods

Study design

- This was a Phase IIb three-arm, two-stage HIV prophylactic vaccine trial with a second randomisation to compare Descovy to Truvada as pre-exposure prophylaxis in healthy adults in the Greater Masaka Region, South-Western Uganda.
- We enrolled and vaccinated 508 at-risk participants aged between 18 and 40 years, from December 2020 to November 2023

Vaccination schedule and Data analysis

- Participants were randomised to receive 4 vaccine doses, and good adherence was defined by the completion of all doses
- Vaccines were administered intramuscularly in the deltoid area of each arm
- Missing a dose would lead to stoppage of further vaccinations
- Using Logistic regression, we analysed baseline characteristics for association with adherence



Results

Participant Characteristics

Characteristic

- Of 508 enrolled, 80.9% (411) were females, median age, 25 (IQR 21-29) Table 1
- Overall, adherence to the vaccination schedule was 74.8%
- Participants aged 25 years and older were 1.6 times more likely to have good adherence to vaccination schedule compared to those aged 18-24 years [adjusted odds ratio (aOR)=1.57, 95% Confidence Interval (CI) 1.04 – 2.40].
- Female participants had lower odds of adhering to the vaccine schedule compared to males (aOR=0.21,95% CI 0.09 0.47) (Table 2).

Table 1: Study participant characteristics by adherence to the vaccine schedule for 508 participants

Poor

Good adherence to

	(Column %)	adherence to vaccine (Row %)	vaccine schedule (Row %)
All	508 (100)	129 (25.4)	379 (74.6)
Age			
18-24	242 (47.6)	71 (29.3)	171(70.7)
25+	266 (52.4)	58 (21.8)	208 (78.2)
Gender			
Male	97 (19.1)	9 (9.3)	88 (90.7)
Female	411 (80.9)	120 (29.2)	291 (70.8)
Marital Status			
Divorced/Separated/Widowed	124 (24.4)	26 (21.0)	98 (79.0)
In a relationship but not living together	122 (24.0)	35 (28.7)	87 (71.3)
Married/Cohabiting	59 (11.6)	12 (20.3)	47 (79.7)
Single	203 (40.0)	56 (27.6)	147(72.4)
Education			
No formal education	17 (3.3)	1 (5.9)	16 (94.1)
Primary	315 (62.0)	76 (24.1)	239 (75.9)
Secondary	176 (34.6)	52 (29.5)	124 (70.5)
Religion			
Christian	382 (75.2)	99 (25.9)	283 (74.1)
Muslim	126 (24.8)	30 (23.8)	96 (76.2)
Employment status			
Sex worker	325 (64.0)	93 (28.6)	232 (71.4)
Subsistence agric/fisheries	35 (6.9)	7 (20.0)	28 (80.0)
Others	148 (29.1)	29 (19.6)	119 (80.4)
Residence			
Fishing	34 (6.7)	5 (14.7)	29 (85.3)
Non fishing	474 (93.3)	124 (26.2)	350 (73.8)

Others: Professional/technical workers, Sales/service workers, Crafts traders, Armed forces, Unemployed Truck/Taxi drivers, market vendor, and househelps/labourers.

Results

Table 2: Factors associated with adherence to vaccine schedule

Characteristic	uOR (95% CI)	p-value	aOR (95% CI)	p-value
Age		0.064	.8	
18-24	1.	.00	1.00	
25+	1.49 (0.997 – 2.2	22)	1.57 (1.04 - 2.40)	0.0343
Sex		< 0.000	1	
Male	1.00		1.00	
Female	0.25 (0.12 - 0.5	51)	0.21 (0.09 - 0.47)	0.0003

uOR= Unadjusted odds ratio; CI= Confidence interval; aOR= adjusted odds ratio

Discussion/Conclusion

- Younger participants (18-24 years) were more likely not to adhere probably due to competing life priorities like education and work[1].
- Women were more likely not to adhere than men probably due to caregiving responsibilities, societal restrictions or concerns over vaccine effects on their reproductive health[2,3].
- Adherence to the vaccine schedule was generally high however, further research to develop a deeper understanding behind lower adherence among women and younger individuals will be vital for equitable uptake of vaccines.
- There is a need to develop targeted vaccine adherence strategies for women and young people.

References

- 1. Robiner, W. N. (2005). Enhancing adherence in clinical research. Contemporary Clinical Trials, 26(1), 59-77. https://doi.org/10.1016/j.cct.2004.11.015
- 2. Kaewkungwal, J., Pitisuttithum, P., Rerks-Ngarm, S., Nitayaphan, S., Khamboonruang, C., Kunasol, P., Suntharasamai, P., Pungpak, S., Vanijanonta, S., Bussaratid, V. and Maek-A-Nantawat, W., 2013. Issues in women's participation in a phase III community HIV vaccine trial in Thailand. *AIDS Research and Human Retroviruses*, 29(11), pp.1524-1534.
- 3. MacDougall DM, Halperin BA, MacKinnon-Cameron D, et alThe challenge of vaccinating adults: attitudes and beliefs of the Canadian public and healthcare providersBMJ Open 2015;5:e009062. doi: 10.1136/bmjopen-2015-009062

Conflict of interest

None to declare

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