

Poster presentation

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P15-13. HVTN 503(Phambili) trial discontinuation of enrolment/vaccination: the impact on trial participant attitudes to vaccine trials and scientific research

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Background

The HVTN 503/Phambili trial, a phase IIB study of the Merck Ad-5 HIV vaccine, suspended enrollment and vaccinations following results of the HVTN502/STEP study. Participants were notified of their treatment allocation and continue to be followed. We investigated the impact of the suspension on trial participants' attitudes towards HIV vaccine trials and scientific research.

Methods

A self-administered questionnaire investigating knowledge and attitudes utilising a five-point likert scale, was administered 12–18 months post suspension at the 4 Phambili trial sites implementing the latest protocol.

Results

Of 544 participants enrolled at 4 sites, 490 completed the questionnaire. 51% understood that vaccination, and 31% that enrolment had been permanently discontinued. Although 85% knew Phambili DSMB recommendations were based on results of the STEP study, only 51% knew that the results showed more infections in the vaccine arm. Although 90% knew they should continue protecting themselves against HIV, only 33% acknowledged trialists' concerns that the vaccine may make them more

susceptible to HIV. Knowledge was similar across sites. 12% had tested for HIV antibodies outside of the trial before unblinding to establish their treatment allocation. 46% felt disappointed, angry or afraid, primarily because the vaccine would not prevent HIV in their community. 79% said they would engage in less risk behaviour. 94% thought the study team had made the correct decision by unblinding them and 96% thought site-participant communication was appropriate. 91% felt they made the right decision to enrol in Phambili and 91% planned to continue attending scheduled visits. 86% support scientific research and 80% would want to participate in future HIV vaccine.

Conclusion

Despite site communications, knowledge levels were low. Importantly, most knew they should continue to protect themselves against HIV. Although almost half of participants reported negative feelings, most attitudes towards trial sites, scientific research and HIV vaccine trials were positive.