



POSTER PRESENTATION

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Enrolment and logistical challenges in TaMoVac 01 Phase I/II HIV trial despite the completion of an earlier (HIVIS-03 trial trial) in Dar es Salaam

M Ngatoluwa¹, P Munseri^{1*}, M Janabi¹, F Mhalu¹, E Sandstrom², M Bakari¹

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Background

Participation of sub-Saharan countries in HIV vaccine trials is important in the fight against HIV/AIDS, and has to be sustained by continued trials. Experiences from earlier trials are expected to influence the design and the performance of subsequent trials. Following completion of HIVIS-03 trial, TaMoVac- 01 trial was initiated. We compare enrolment experiences between the two trials.

Methods

The HIVIS-03 trial, conducted between 2007 - 2010 recruited 60 volunteers from the Police force in Dar es Salaam.

The subsequent TaMoVac- 01 trial has recruited 62 volunteers from the Police and Prisons force, and youths at IDC.

Results

Enrollment of volunteers into the HIVIS-03 took 12 months while the TaMoVac-01 trial took 13 months.

Screened: enrolled ratio was 3:1 for HIVIS-03 trial, while for TaMoVac-01 8:1. Reasons for screen-out in the TaMoVac-01 trial were influence of family, misconception, clinical and laboratory abnormalities.

Recruitment of females was a challenge in the HIVIS-03 trial, but was unnoticed in the TMV-01 trial, this could be due to inclusion of youths. Misconceptions in the Police force remain an obstacle to recruitment despite regular education sessions.

Other challenges were: Poor adherence to schedules, due to competing prioritization of employment

requirements; difficulties in communication with volunteers without phones.

Most challenges were addressed through collaboration with the concerned authorities in the respective cohorts.

Conclusion

Recruitment challenges continued in the TMV-01 trial despite our experiences with HIVIS-03 trial. Enhanced Community engagement and timely action by the researchers is necessary to ensure a smooth conduct of the trials.

Author details

¹Muhimbili University of Health and Allied Sciences, Tanzania, United Republic of. ²Karolinska Institutet, Sweden.

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¹Muhimbili University of Health and Allied Sciences, Tanzania, United Republic of
Full list of author information is available at the end of the article