

Abstract

TUPE0416 - Informed consent in a randomised trial of HSV-2 suppressive treatment for HIV prevention, Tanzania

D. Watson-Jones¹, M. Rusizoka¹, K. Mugeye¹, J. Chagalucha², H. Weiss³, D. Ross³, F. Mohammed¹, C. Tanton³, R. Hayes³

¹African Medical & Research Foundation, Mwanza, Tanzania, ²National Institute for Medical Research, Mwanza, Tanzania, ³London School of Hygiene & Tropical Medicine, Department of Infectious & Tropical Diseases, London, United Kingdom

Background: Ensuring comprehension of randomised clinical trial concepts poses challenges for informed consent. A novel informed consent process has been developed for a randomised, double blind placebo-controlled trial of HSV suppressive therapy trial in Tanzania. The trial aims to determine whether aciclovir 400mg bd can reduce HIV incidence and HIV and HSV2 genital viral shedding in 1300 female bar, hotel and other facility workers.

Methods: The informed consent process has 3 phases. Trial information is given initially at facilities and then to individual women when they attend screening for HIV and HSV2 antibodies. At the later enrolment visit, they are given written and verbal trial information and asked to look at a picture book with an accompanying audio tape that explains the trial rationale, aims and procedures. A checklist of 8 questions is administered to check understanding. Women who fail to give correct answers have the relevant information explained again and understanding is re-checked. They are enrolled when the interviewer is satisfied that they understand the trial.

Results: To date, of 1011 eligible HSV2+ women completing the assessment pre-consent, 1001 have been enrolled having demonstrated adequate understanding of the trial. After trial information had been given and before consent, the initial assessment of understanding showed that 78% did not understand randomisation, 75% did not understand placebo, 68% did not understand blinding and 64% did not understand that they could withdraw at any time and still access services. Almost all women were able to answer correctly once these concepts were individually explained again. 10 women did not understand the study and were not enrolled.

Conclusions: Despite a detailed multistep informed consent process for a clinical trial, misunderstanding of key issues was frequent. A simple tool to assess understanding allowed the team to explain specific problem concepts to ensure adequate understanding prior to enrolment and randomisation.