

AB36 Pilot study to predict estimated screening sample size for Phase III Microbicide Trial.

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ABSTRACT TEXT

Background:

An MDP Pilot Study was done to optimise trial procedures developed for a proposed MDP 301 Phase III randomised placebo-controlled trial. Women were screened to evaluate whether they fulfilled the eligibility criteria for enrolment into the MDP Pilot study using a Placebo gel.

Methodology:

10 factors were in the inclusion criteria; one was that participants had to be HIV negative at screening. In order to be enrolled in the study, women had to meet all of the stipulated inclusion criteria. Data were obtained through the Eligibility Form 1 where all the inclusion and exclusion criteria were listed. A total of 50 eligible women were enrolled into the study at each site.

Results:

98 women were screened to enrol 50 participants who fulfilled the eligibility criteria. 44 women did not meet certain specified criteria; 38 out of 44 were screened out for being HIV positive and 6 were excluded for all the other criteria.

Conclusion:

Exclusion because of a positive HIV test made the bulk of exclusions. High HIV prevalence resulted in the screening of a large number of participants in order to reach the enrolment target among women at high risk for infection. Results obtained from the MDP Pilot Study assisted in projection of the number of women that need to be screened in order to reach the enrolment target of 2000 for the MDP Phase III Trial.

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