

Predictors of pregnancy in a phase III Microbicide trial of PRO 2000/5 conducted in Johannesburg.

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Introduction:

Phase III trials of candidate Microbicides are currently recruiting women of reproductive age to participate in the trials. Pregnancy in these trials is an undesirable outcome as it results in loss of women years of follow up and ultimately diminishes the power of the trial to show effect. Describing factors associated with pregnancy is challenging. Preventing unwanted pregnancies by adequate contraception is important for both the safety of participants and for trial integrity. Although contraception is provided by the trial site, the number of unplanned pregnancies remains high. This paper aims to assess factors associated with unplanned pregnancies in order to help with better provision of and adequate use of contraception.

Methods:

As part of the phase III trial of PRO 2000/5, sexually active, HIV negative women who are not pregnant are invited to take part in the trial. During the informed consent process women are informed that participants should avoid pregnancy during their time of participation as the safety of the gel in pregnancy is not known and that gel use will be discontinued for the rest of their stay in the trial if a participant is found to be pregnant. Pregnancy tests are conducted at each monthly visit. Information about contraception use is sought at all visits and each participant is counseled about reliable form of contraception. Those not already on a reliable method are counseled and offered hormonal contraception at the enrolment visit. Secondary analysis of data collected on a prospective cohort of MDP 301 will be used to answer the following questions:

- Incidence of pregnancy
- Factors associated with pregnancy:
 - Participant demographics,
 - Contraceptive use,
 - Reasons for non-use of contraception
 - Type of contraception a month preceding pregnancy.
 - Number of pregnancy that are terminated.

Results:

To date the incidence of pregnancy is 14.92 per 100 person-years of follow up. A large number of these women were not planning a pregnancy and have opted for termination of pregnancy. Four out of 54 pregnant participants (7.41%, 95% CI 0.43 – 14.39) were not on any form of contraception at enrolment and only 1 participant was planning to fall pregnant.

Conclusions

Knowing the extent to which contraceptive non-use and imperfect use account for unintended pregnancies, as well as risk factors for nonuse, will help the study team support effective contraceptive use. In addition, investigations into the acceptability of less participant-reliant methods such as intra-uterine contraceptive devices (IUCD) are underway.