PB78 The challenges of recruitment and enrolment into a safety and acceptability study of the diaphragm and ACIDFORM gel or placebo.

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ABSTRACT TEXT
Background:
There is renewed interest in the reintroduction of the diaphragm as an HIV prevention technique. The diaphragm used in combination with a microbicide gel provides a possible double prevention method. Diaphragm use requires some skill and professional assistance in fitting and it has largely been removed from public service medicine in the developing world for these reasons. This CONRAD “Safety and Feasibility Study of the Diaphragm Used with ACIDFORM Gel or KY® Jelly” study provided some interesting insight into the acceptability of the diaphragm.

Methods:
Low risk sexually active women of reproductive age were screened for eligibility of the study. This included HIV testing, medical history, physical exam, pelvic examination with STI testing and urine pregnancy testing. At enrollment consenting participants were randomized blindly to one of two groups (active gel or placebo). Both groups used a diaphragm with the gel. Follow up lasted 6 months during which participants were seen in the clinic monthly.

Results:
2287 women were seen in the field — 1176 said they were interested in the study (not all made appointments) and 1111 were refusers i.e. they declined participation in the study. Reasons given for refusal included: not been sexually active, pregnant or planning pregnancy, breast feeding, already HIV positive, partner influence, work or school commitments, not willing to use diaphragm, against religion and not a permanent resident in Johannesburg. Accrual took 11 months. A total of 712 volunteers (+/- 3.2:1) were pre-screened — 40% were HIV positive and ineligible. 276 volunteers (+/- 2.6:1) were screened — 42.7% screening and 13.4% enrollment failures for various reasons. 120 participants were enrolled (2.3:1 screening and 19.1:1 field) and of these 19 were discontinued (no discontinuations were product related). Only 3 participants were lost to follow-up.

Conclusion:
A number of challenges were encountered in recruiting women for the study. A large number of women needed to be prescreened and screened to enroll the 120 target. Difficulties were experienced in excluding high risk women e.g. women who knew their HIV positive status and used the clinic for repeat testing. Low risk women are needed for safety studies, but testing products on HIV positive women would also be important.

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