

Abstract

BACKGROUND:

Female participants in AIDS candidate vaccine clinical trials must agree to use effective contraception to be enrolled into the studies, and for a specified period after vaccination, since the candidate vaccines' effects on the embryo or foetus are unknown.

OBJECTIVES:

To review data on female participants' pregnancy rates from phase I and IIA AIDS vaccine clinical trials conducted at the Kenya AIDS Vaccine Initiative (KAVI) and to discuss the challenges of contraception among female participants.

DESIGN:

Descriptive observational retrospective study.

SETTING:

KAVI clinical trial site, Kenyatta National Hospital and University of Nairobi, Kenya.

SUBJECTS:

Thirty nine female participants were enrolled into these trials. They received family planning counselling and were offered a choice of different contraceptive methods, as per the protocols. All contraception methods chosen by the participants were offered at the study site at no cost to the participant.

RESULTS:

Four women conceived during the study period when pregnancies were to be avoided. All four had opted for sexual abstinence as a contraceptive method, but reported having been coerced by their partners to have unprotected sexual intercourse.

CONCLUSION:

Abstinence is clearly not a reliable contraceptive option for women in developing-country settings. Effective female-controlled contraceptives, administered at the clinical trial site, may empower female participants to better control their fertility, leading to more complete clinical trial data.