Microbicide for prevention of HIV in women

The protocol you have in front of you describes a Phase 2b, multisite, double-blind, randomized control trial.

It will take place in several African countries. The formulation being tested is a vaginal microbicide for prevention of HIV in women. The safety and efficacy of the formulation have been tested in animal studies and in phase 1 and 2 trials. These highly promising findings are described in the protocol.

Study participants will be recruited from the network of community family planning clinics that exist across the region. Half of the women recruited will be provided with the test formulation. The other half will be given a placebo which looks exactly like the microbicide and is administered in the same way.

Because there is no successful drug-based method of HIV prevention readily available, we believe a placebo is justified.

The family planning clinics where the women will be recruited already provide free access to family planning methods, maternity-related services, and limited diagnosis and care for sexually transmitted infections, also known as STIs. However, patients must pay for medications and physicians at these clinics often prescribe drugs that patients cannot afford.

The Nort American agency funding this study will provide additional funds to test for and freely treat viral and bacterial STIs for study participants in both study arms and will pay for certain other prescribed drugs, which are otherwise unaffordable.

Finally, participants who present with problems unrelated to the study, such as diarrhea and malaria, will be referred to a doctor on the study team and will receive the necessary treatment without charge.

These services are exactly what would be offered in the sponsor's country if the trial were to be held there. The funding agency and researchers believe that research participants are owed the same standard of care that they would receive in the sponsor's country.

The informational material that will be provided to potential participants explains the possible benefits and harms in detail. Before giving informed consent, the women must demonstrate through their answers to a short questionnaire that they understand the basic facts about the study.

Thank you for considering this important study.