



ICRH

INTERNATIONAL CENTRE FOR REPRODUCTIVE HEALTH

*Improving sexual and reproductive health
through research, training and adapted interventions*

Novel biomarkers to measure safety of microbicides

Summary

Products used in a number of recent microbicide trials have turned up unexpected safety results. There is a need for more reliable safety biomarkers for phase I and II vaginal microbicide trials. Better understanding and measurement is needed of the effect of substances introduced in the vaginal environment. The project will study a variety of African female target populations in four African settings to identify and improve both clinical and laboratory methods and findings in search of more reliable safety biomarkers. The consortium offers the combination of multidisciplinary experience and cutting-edge technology to make this possible.

Objectives & Methods

a. Biomarkers

We propose to characterize biomarkers of inflammation, epithelial integrity, immune activation, and antimicrobial activity in the cervicovaginal environment of healthy HIV-negative adult women at low risk for HIV, healthy HIV-negative adult women at high risk for HIV, HIV-negative adult women with BV, HIV-negative adult women using traditional vaginal practices, HIV-negative adult pregnant women, HIV-negative adolescents, healthy HIV-positive adult women, and microbicide and placebo gel users (the latter using stored specimens) in Kenya, Rwanda, Tanzania and South Africa. We will also conduct traditional microbicide safety assessments (which are mostly clinical), and will correlate the biomarkers with these traditional assessments. The expected outcomes are the identification of promising biomarkers that could be introduced in the next generation of microbicide safety trials, and baseline data on these biomarkers against which future assessments in women who are using candidate microbicide products can be compared.

b. Trial preparedness

Before a microbicide is marketed, its safety will have

to be established in special population groups (such as adolescents, pregnant women and high frequency users). These groups are not typically included in standard safety and efficacy trials. In this study, we will characterize these special population groups, with an emphasis on recruitment and retention procedures. The expected outcomes are recruitment and retention plans for these special population groups, and a better understanding of sexual and reproductive behaviour in these groups.

c. Adapted technologies

In order to study biomarkers, and characterize special population groups for microbicide trials, a strong collaboration between different countries and different disciplines is needed. We need to bring together clinicians, laboratory scientists, social scientists, data staff and administrative staff from institutions in sub-Saharan Africa that are conducting microbicide trials and from institutions in Europe that possess very specific expertise (for example, expertise in cutting edge laboratory techniques). However, the consortium of scientists on this proposal will decide together which biomarker tests are appropriate for future technology transfer to the African sites. The expected outcome is a technology transfer plan.

Partners

ICRH - Kenya, Projet Ubuzima, Rwanda, MITU/NIMR, Tanzania, RHRU, South Africa, Institute for Tropical Medicine and Ghent University, Belgium, AMC-CPCD, The Netherlands, London School of Hygiene and Tropical Medicine and MRC, UK

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