Microbicide Optimization Through Innovative Formulation for Vaginal and Rectal Delivery

From 2012-10-01 to 2016-03-31, closed project

Objective

The 40% protection against HIV-1 infection with vaginally-applied tenofovir gel demonstrated in the CAPRISA004 trial, has emphasized development of anti-retroviral (ARV)-based microbicides. Combining ARVs in a single product may provide increased protection. Development of a generally applicable formulation platform for combining ARVs (even if chemically incompatible) and understanding of the processes (drug uptake, efflux and metabolism) that determine tissue levels of microbicide are two important gaps in knowledge necessary for microbicide development. We propose to identify drug uptake and efflux transporters in cervicovaginal tissue and to use this information together with data on drug transporters from colorectal tissue to develop improved in vitro cell-based systems for biopharmaceutical screening. We also propose to develop a standardized drug encapsulation and formulation system that will allow insertion of any drug combinations. Informed by data on drug uptake, efflux and metabolism, these formulations will be further modified either by beneficial drug-drug interactions or by including selective inhibitors or inducers of drug transporters to optimize drug concentrations at target tissue sites. Comparative studies of drug transporters will also be performed in two important animal models, namely non-human primates (virus challenge) and rabbit (regulatory toxicology). Optimised drug formulations will be tested in vitro and will undergo pharmacokinetic and pharmacodynamics studies in the animal models. Project outcomes will include a detailed description of drug transport in colorectal and cervicovaginal tissue to provide a rational basis for microbicide formulation, platform technology for formulating microbicide combinations optimized for vaginal or rectal delivery and prototype microbicide products for phase I clinical trial. The proposal should impact significantly on development of improved microbicides to prevent HIV infection.

Related information

Result In Brief

Novel drug formulations against HIV

Report Summaries

Final Report Summary - MOTIF (Microbicide Optimization Through Innovative Formulation for Vaginal and Rectal Delivery)
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Subjects
Scientific Research

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