Temperature recording vaginal ring for accurate measurement of user adherence

Objectives and Background

Vaginal rings are already marketed for various clinical indications, including contraception, hormone replacement therapy and luteal phase support, and are being actively developed as HIV microbicide and multi-purpose prevention technology (MPT) products. The sustained/controlled nature of vaginal ring drug delivery systems generally offers increased user adherence compared with on demand products. To date, all microbicide clinical trials, including the CAPRISA-004, VOICE and FEM-PrEP studies, have relied on self-reporting questionnaires as a measure of user adherence. However, the reliability and validity of these adherence data are questionable; participants are likely to report good adherence given the expectations to comply with study protocols. More objective, quantitative and accurate methods for assessing adherence are needed.

Geographic location

Global, but as a first instance, for countries in sub-Saharan Africa where topical pre-exposure prophylaxis introduction is anticipated.

Main deliverables

In collaboration with the University of Belfast, the RHR Department demonstrated proof-of-concept of a novel, vaginal temperature-recording device comprising a miniature temperature recording implant encapsulated within non-medicated silicone elastomer vaginal tubing. Vaginal administration in cynomolgus macaques enabled accurate and continuous monitoring of body temperature, both the small changes associated with the normal diurnal pattern and the larger changes associated with removal and re-insertion of the vaginal device.

Partners

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Sources of funding

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