

0.5% PRO2000/5 Rectal Microbicide Safety Study

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- 0.5% PRO2000/5 has shown promise as a vaginal microbicide in HPTN035 Phase IIb
- It is already being tested in a Phase III, MDP301 which will report at the end of 2009
- If MDP301 provides sufficient evidence, an application for worldwide license for vaginal use will be made
- The rectal safety trial, MDP103, is planned to support this application for license
- MDP103 has been approved by a multi-centre research ethics committee and the UK regulatory authority

- Study Design

- 2 sites: St. Mary's, London and York NHS Trust
- Stage 1 - 25 HIV negative participants
- Stage 2 - 10 HIV positive participants
- Must be men who have sex with men and currently in a monogamous sexually active relationship
- Partner must also consent to the study
- Both partners must have the same HIV status
- Double blind randomisation to receive either 2mL placebo gel or 2mL of 0.5% PRO2000/5 gel
- Single dose, 7days free then 7days twice daily gel
- RAI at least once in 7 day dosing period

- What is involved
 - 28 days study duration minimum
 - 6 clinic visits
 - At least 5 anoscopies (look inside the rectum with a magnifying lens and camera)
 - 3 (possibly 4) rectal biopsies – removing a small piece of rectal tissue
 - A total of 75 mL of blood will be taken during the study
 - Time and travel will be reimbursed

- Timelines

- Trial start currently dependent on outcome of Phase III
- Planned to begin in November 2009
- Enrolment to phase 1 by May 2010
- Enrolment to phase 2 by Dec 2010
- Results May 2011