ONGOING AND PLANNED CLINICAL TRIALS OF MICROBICIDE CANDIDATES

April 2012

AVAC
Global Advocacy for HIV Prevention

Study Name	Phase	Start Date	Sponsor/Funder [1]	Locations [1]	Population [2]	Intervention arms [3]	Status/Expected Completion
Open Label							
CHOICE (MTN 018)	Phase IIIb/ Open label follow-on	Proposed start date 2013	Gilead, MTN, NIAID, NICHD, NIMH	South Africa, Uganda, Zimbabwe	HIV-uninfected former VOICE participants	Daily oral TDF/FTC	Pending results of VOICE / Q4 2015
CAPRISA 008	Open label	Proposed start date Q2 2012	CAPRISA, MAC AIDS Fund, South African DST, USAID through CONRAD	South Africa	700 women	1% tenofovir gel up to 12 hours before vaginal intercourse and within 12 hours following intercourse	Under review by the South African Medicines Control Council (MCC)
Phase III (safety and effectiveness)							
ASPIRE (MTN 020)	Phase III	Q2-Q3 2012	IPM, MTN, NIAID, NIMH	Malawi, South Africa, Uganda, Zambia, Zimbabwe	3,476 women	4-week vaginal dapivirine ring	Pending / Q4 2014 - Q1 2015
The Ring Study (IPM 027)	Phase III	March 2012	IPM	South Africa, Rwanda, Malawi	1,650 women	4-week vaginal dapivirine ring	Planned / 2015
FACTS 001	Phase III	October 2011	BMGF, CONRAD, South Africa DST, South Africa National DOH, USAID	South Africa (Cape Town, Soweto, Rustenburg, Soshanguve, GaRankuwa, Tembisa, Yeoville, Ladysmith, Pietermaritzburg)	Minimum of 2,200 women	1% tenofovir gel up to 12 hours before vaginal intercourse and within 12 hours following intercourse	Enrolling / Q1-Q2 2014
Phase II, IIb (safety, adherence, acceptability, feasibility, effectiveness)							
MTN 017	Phase II	Q1 2013	CONRAD, Gilead, MTN, NIAID, NIMH	Peru, South Africa, Thailand, United States	186 men who have sex with men and transgender women	Reformulated (reduced glycerin) 1% tenofovir gel used rectally	In development / Q3-Q4 2014
VOICE (MTN 003)	Phase IIb	September 2009	CONRAD, Gilead, MTN, NIAID, NICHD NIMH	South Africa, Uganda, Zimbabwe	5,029 women	Daily oral TDF/FTC *Daily oral TDF and daily 1% tenofovir gel arms dropped for futility based on data from DSMB reviews.*	Fully enrolled / Q1 2013
FACTS 002	Phase II	TBD	CONRAD, USAID	South Africa (Cape Town)	60 young women (16-17 years old)	1% tenofovir gel used daily	In development / TBD
Phase I/II (safety, adherence, acceptability, feasibility)							
IPM 015	Phase I/II	April 2010	IPM	Kenya (Kisumu), Malawi (Lilongwe), South Africa (Brits, Edendale, Mbekweni, Ladysmith, Masiphumelele, Nyanga, Pinetown), Tanzania (Moshi)	280 women	4-week vaginal dapivirine ring	Data analysis / Q1 2012
MTN 005	Phase I/II	June 2011	MTN, NIAID, NIMH, Population Council	India, United States	252 women	Placebo vaginal ring	Enrolling / Q1-Q2 2013

IPM 014A	Phase I/II	November 2009	IPM	Kenya (Kisumu), Malawi (Blantyre), South Africa (Brits, Ladysmith, Mbekweni, Pinetown, Nyanga), Rwanda (Kigali)	280 women	Once-daily dapivirine vaginal gel	Data analysis / Q2 2012
IPM 014B	Phase I/II	September 2009	IPM	South Africa (Brits, Mbekweni and Masiphumelele)	100 women	Once-daily dapivirine vaginal gel	Data analysis / Q2 2012
IPM 020	Phase I/II	July 2009	IPM	United States (Bronx, NY; Los Angeles, CA; Chicago, Il; Baltimore, MD; Birmingham, AL)	128 women	Once-daily dapivirine vaginal gel	Data Analysis / Q2 2012
Phase I (safety, adherence, acceptability, feasibility)							
CONRAD 122	Phase I	TBD 2013	CONRAD	United States	40 men and women	SILCS diaphragm and 1% tenofovir gel	Protocol in development
CONRAD 123	Phase I	TBD 2013	CONRAD	TBD	36 women	SILCS diaphragm and TFV	Protocol in development
NNRTI Microbicide Gel Formulation	Phase I	Q3 2012	Population Council, USAID	United States (sites TBD)	30 women	MIV-150/Zinc acetate vaginal gel vs. carageenan-based placebo gel	Planned / Q1 2013
CONRAD 121	Phase I	Q4 2012	CONRAD	United States (Eastern Virginia Medical School) and TBD	68 women	TFV-LNG IVR ring	Protocol in development
MTN 014	Phase I	Q4- 2012	CONRAD, MTN, NIAID, NIMH	South Africa, United States	28 women	Reformulated (reduced glycerin) 1% tenofovir gel used rectally and vaginally	In development / Q1 2014
MTN 011	Phase I	Q2-Q3 2012	CONRAD, MTN, NIAID, NIMH	United States	48 heterosexual couples	1% tenofovir gel used around the time of vaginal intercourse or daily	In development / Q2-Q3 2013
CONRAD 120	Phase I	Q2 2012	CONRAD	United States (Eastern Virginia Medical School) and TBD	36 women	1% tenofovir vaginal ring	Planned / Q4 2012
CONRAD 118	Phase I	Q2 2012	CONRAD	United States (University of California, San Francisco; Bronx-Lebanon Hospital)	54 women	Interaction of TFV gel and antifungal cream, antimicrobial gel and contraceptive ring	Protocol in development
CONRAD 117	Phase I	Q2 2012	CONRAD	United States (Eastern Virginia Medical School) and TBD	48 women	TFV/FTC and TFV only fast dissolve vaginal tablets	TBD
CONRAD 114	Phase I	January 2012	CONRAD	United States (Eastern Virginia Medical School; University of Pittsburgh School of Medicine); Dominican Republic (PROFAMILIA)	72 women	Depo-provera; 1% tenofovir vaginal gel used after vaginal intercourse	Ongoing / 2012-2013

MTN 013 / IPM 026	Phase I	November 2011	IPM, MTN, NIAID, NIMH	United States	48 women	Vaginal dapivirine ring (25 mg), vaginal maraviroc ring (100 mg), vaginal dapivirine-maraviroc ring (25 mg dapivirine + 100 mg maraviroc) for 28 days	Enrolling / Q1-Q2 2013
MTN 008	Phase I	April 2011	CONRAD, MTN, NIAID, NICHD	United States	90 pregnant women and 15 breastfeeding women	1% tenofovir gel used for 7 days	Enrolling / Q2-Q3 2013
MTN 012 / IPM 010	Phase I (penile tolerance)	April 2011	IPM, MTN, NIAID, NIMH	United States	48 men	Once-daily dapivirine vaginal gel used for 7 days	Results pending Q2 2012
Project Gel	Phase I	October 2010	CONRAD, NICHD, NIMH	Puerto Rico, United States	240 MSM	1% tenofovir rectal gel once daily for 7 days and placebo rectal gel prior to rectal intercourse	Ongoing / December 2012
AF 020	Phase I	February 2009	AECOM, NIAID	United States	36 women	Amphora/ACIDFORM vaginal gel	Data analysis / Q2-Q3 2012
Other							
Effects of Tenofovir on Caprisa samples	Pre-clinical	Q4 2013	CONRAD	EVMS and TBD	TBD	Tenofovir	Planned / 2014
Vaginal Microbicide Adherence	Validation	Q2 2012	MTN, Population Council, RTI	United States (AECOM)	Part 1: 15 couples Part 2: 40 women	Dye Stain Assay (DSA), UV-Light, and Wisebag™	Planned / Q4 2012
EMBRACE (MTN 016)	Pregnancy exposure registry	October 2009	MTN, NIAID, NICHD	Malawi, South Africa, Uganda, Zambia, Zimbabwe, United States	500 women and 300 infants	N/A	Enrolling / May 2013
MTN 009	Cross-sectional resistance study	September 2010	MTN, NIAID	United States	1074 women	N/A	Results reported Q1 2012
MTN 003C	MTN 003 (VOICE) Community Sub-study	July 2010	MTN, NIAID, NIMH	South Africa	275 participants (includes women in VOICE, their male partners, CAB members and community stakeholders)	N/A	Enrolling / Q1 2013
Sex-Workers Study	Feasibility	February 2010	NIH, Population Council, USAID	India (Nellore, Andhra Pradesh)	267 female sex workers	HEC placebo vaginal gel	Data collection completed December 2010; analysis ongoing
MTN 003B	MTN 003 (VOICE) bone mineral density sub-study	November 2009	Gilead, MTN, NIAID	Uganda, Zimbabwe	518 women	Oral TDF; oral TDF/FTC	Fully enrolled / Q1 2013
MTN 015	Seroconverter protocol	August 2008	MTN, NIAID	Malawi, South Africa, Uganda, Zambia, Zimbabwe	500 HIV-positive women	N/A	Enrolling / May 2013

DST - South Africa Department of Science Technology; DOH - South Africa National Department of Health; EVMS - Eastern Virginia Medical School; IPM - International Partnership for Microbicides ; MTN - Microbicide Trials Network; N/A - Not applicable; RTI - Research Triangle Institute; NIAID - United States National Institute of Allergy and Infectious Diseases; NICHD - Eunice Kennedy Shriver National Institute of Child Health and Human Development; NIH - United States National Institutes of Health; NIMH - United States National Institute of Mental Health (NIMH); TBD - To be determined; TDF - Tenofovir disoproxil fumarate; TFV - Tenofovir; USAID - United States Agency for International Development

1. Countries, sponsors and funders are listed alphabetically.
2. The studies listed in this table are HIV prevention trials and thus are looking at whether the experimental intervention reduces the risk of HIV infection—trial participants are HIV-negative, unless otherwise noted.
3. In addition to the assigned intervention, all trial participants receive a standard HIV prevention package, possibly including but not limited to: risk reduction counseling, condom provision and behavioral interventions.