

MDP302

A randomised placebo-controlled trial to assess the effectiveness of a single dose of 1% tenofovir vaginal gel, in relation to BAT24 dosing, in preventing acquisition of HIV and HSV2, and to compare adherence between the two regimens

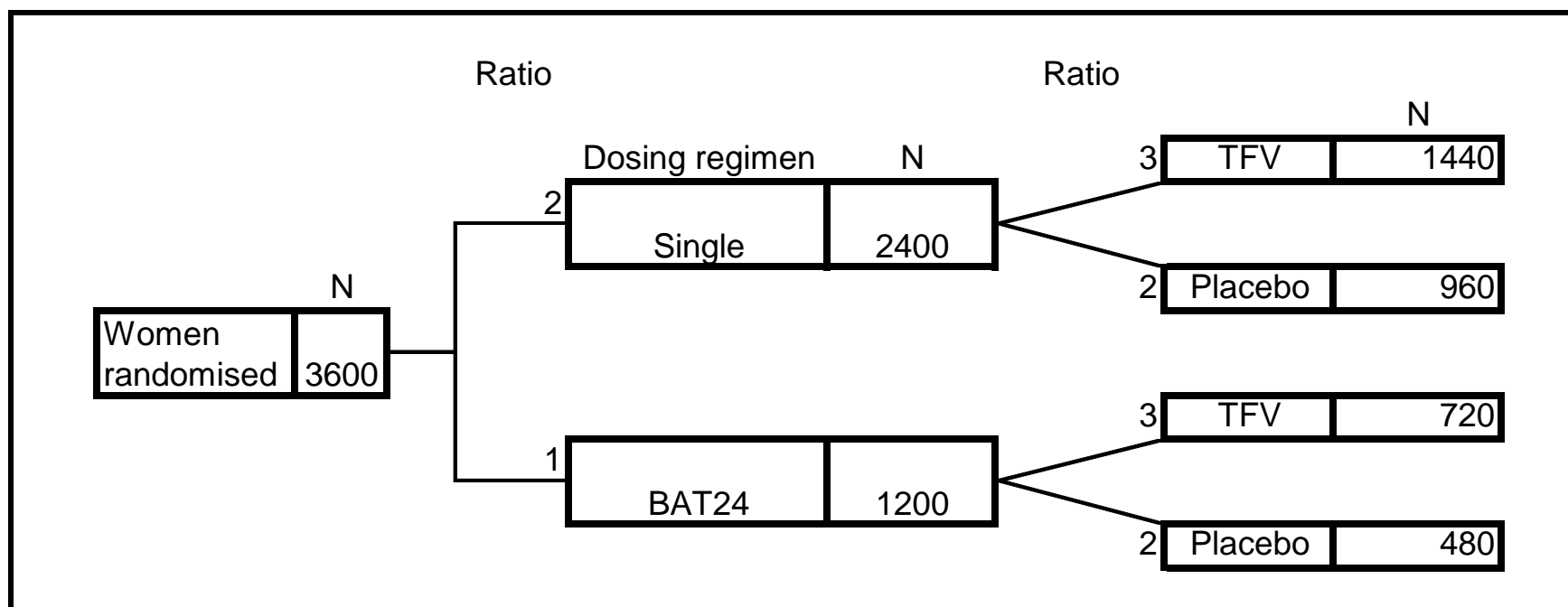
MDP 302 sites and capacity



Partner	# in 12m	Population	Incidence /100py
MRC/UVRI Uganda Unit in Entebbe and Masaka, Uganda	1000	Sero-discordant couples	4.8 (3.7-6.4) MDP301
Mwanza Intervention Trials Unit in Geita and Mwanza, Tanzania	1000	High risk young women in bars	4.4 (3.1-6.1) EDCTP cohort
University of Zambia in Mazabuka, Zambia	800	General population	4.2 (3.2-5.6) MDP301
CISM in Manhica and Maputo, Mozambique	800	General population	5.0 (3.1-8.0) EDCTP cohort

Total number of participants =3600; pooled HIV incidence=4.6 /100py

Design



Main outcomes



- Effectiveness of a single dose applied before sex, or failing that as soon as possible afterwards
 - in preventing acquisition of HIV at or before 76 week endpoint
 - in preventing acquisition of HSV2 at or before 76 week endpoint
 - in relation to the effectiveness of BAT24 in the same populations
- Safety including
 - Less frequent HIV testing (3m to 6m if no resistance)
 - Adolescents
 - ***Pregnant women***
- The extent to which differences in ***triangulated adherence*** explains the differences in effect (single dose compared to BAT24) ***within each country***

HIV: Sample size and power



POWER	
Incidence in control arm /100 py	50% reduction in HIV incidence
3.5	86%
4.0	90%
4.5	93%

Single dose versus placebo comparison

- 18 months follow-up
- 50% effect (reduction in HIV incidence)
- 4.0/100py HIV incidence in placebo arm
- 5% sig (2-sided)
- 90% power

HSV2: sample size and power



POWER	
Incidence in control arm /100 py	50% reduction in HSV2 incidence
9.0	77%
10.0	81%
11.0	84%

Single dose versus placebo comparison

- 18 months follow-up
- 50% effect (reduction in HSV2 incidence)
- 10/100py HSV2 incidence in placebo arm
- 5% sig (2-sided)
- >80% power

Adherence: sample size and power



Single dose versus BAT24 comparison

N	Mean % difference in adherence	Power
759	5%	90%
192	10%	90%

- 2:1 randomisation Single:BAT24
- 75% adherence to BAT24 (based on CAPRISA)
- SD=20% (based on MDP301)
- 5% significance (2-sided)
- ≥ 800 per centre allows within centre comparisons