

BASELINE CHARACTERISTICS, ANTIRETROVIRAL RESISTANCE PROFILE AND CLINICAL EVENTS IN THE OPTIMA TRIAL: A PRELIMINARY REPORT

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Background: The OPTIMA trial is a collaboration between the U.S. Department of Veterans Affairs, U.K. MRC and Canadian CIHR. OPTIMA is an ongoing strategy trial for patients with virologic failure and multi-drug resistant (MDR) virus.

Methods: Patients (target N=504) with HIV RNA >2,500 copies/mL, CD4 < 300/mm³ on ARV therapy are randomized in a 2 by 2 factorial to a 3 month antiretroviral drug-free period (ARDFP) vs. no ARDFP followed by a new standard ART (≤ 4 ARVs) or MegaART (≥ 5 ARVs) versus no ARDFP (immediate change to new ARV regimen of standard vs. MegaART). AIDS events/death and adverse events are recorded for primary and secondary endpoints, respectively.

Results: 264 patients (96% male, mean age 48) have been enrolled thus far. Baseline mean HIV RNA = 4.72 log₁₀/ml and CD4 = 126 cells/mm³. ARV history included >2 PI (64%), NNRTI (96%) and NRTI (100%). Broad virtual phenotypic resistance to all ARV classes was seen. To date, there has been no loss to follow-up and the overall crossover rate is 6%. There have been 65 new or recurrent AIDS events, 23 deaths (9 AIDS related), 286 Grade 3/4 AEs in 69 patients, 75 of which lead to an ARV regimen change in 30 patients. Ongoing analysis by the DSMB has determined that there are no safety concerns.

Conclusions: Although still blinded to treatment strategy, an ARDFP has not resulted in safety concerns. The clinical response to standard or MegaART, whether preceded by an ARDFP or not, will continue to be examined.