

Exploratory analysis of a double-blind randomized trial of dronabinol for nausea in HIV+/AIDS patients receiving highly active antiretroviral therapy (HAART)

C. Cohen¹, L. Barbato², A. Shapira², F. Carter², V. Baranowski²

Introduction: Patient adherence is a determinant of success on HAART. Nausea is one of the prominent side effects reported with HAART and can impede patient adherence. A double-blind, randomized pilot study was conducted exploring the efficacy of dronabinol in treating nausea in HIV+/AIDS subjects.

Methods: Subjects were divided into 2 cohorts. Cohort A subjects previously or currently experienced nausea/vomiting while on HAART. Cohort B subjects newly started or switched to HAART (from a regimen not producing nausea/vomiting). Subjects were randomized to either dronabinol or placebo for at least two weeks beginning treatment with 5 mg BID. Titration (max 40 mg/day) was allowed. Post-hoc exploratory analyses were performed on a subgroup of Cohort A who took study medication, had a post-baseline efficacy evaluation, and had a baseline VAS \leq 5 mm. Complete response of nausea, vomiting/retching episodes, duration of nausea/vomiting/retching, intensity of nausea (0-100 mm), and MQOL-HIV Survey Nausea Item (7-point scale) were evaluated.

Results: Cohort A subgroup included 29 of 77 subjects (15 dronabinol; 14 placebo). At Week 1, a change of -15.3 mm in dronabinol relative to the -5.9 mm in placebo showed a favorable trend ($p=0.073$). For Week 2, favorable dronabinol changes of -27.9 mm were observed compared to -14.5 mm in placebo ($p=0.148$). At Week 2, mean vomiting/retching episodes were lower on dronabinol compared with placebo, 7.2 versus 12.9 ($p=0.056$). The MQOL-HIV Survey Nausea Item showed changes of -1.4 in dronabinol at endpoint, compared to -0.6 in placebo. Treatment differences were not observed for other efficacy endpoints. The incidence of AEs was 54% in dronabinol and 44% in placebo, with no SAEs reported.

Conclusions: Dronabinol is safe and may improve HAART-related nausea.