

**The Effect of Smoked Marijuana on Chronic Neuropathic and Experimentally-Induced Pain in HIV Neuropathy:
Results of an Open-Label Pilot Study**

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Painful peripheral neuropathy continues to be a significant clinical problem in patients (pts) with HIV infection. Preclinical studies suggest that cannabinoids may be effective in neuropathic pain syndromes.

Methods: Open-label pilot inpatient study conducted over nine days in the General Clinical Research Center. Eligible subjects with confirmed HIV neuropathy and persistent pain greater than or equal to 30/100 as assessed by a 7-day pain diary were enrolled. All subjects had prior experience smoking marijuana but had ceased for 30 days prior to admission. After a 2-day lead-in period, pts smoked one 3.56% THC-containing marijuana cigarette three times daily for 7 days. A heat-capsaicin model induced experimental pain that was also evaluated. Pts experiencing a $\geq 30\%$ reduction in their neuropathy pain were assessed as responders. The pilot study was designed to assess the effect size and calculate the sample size for a follow-on randomized, placebo-controlled trial if warranted.

16 pts (14 men), median age 43 with an average of 6 yrs duration of neuropathy were enrolled. Neuropathy was related to HIV alone (3), nucleoside therapy (8) or both (5). The mean baseline average daily pain value of 47/100 dropped to 40/100 following the 2-day lead-in. Marijuana smoking caused a drop in pain score to 20/100 with 10/16 pts experiencing a $\geq 30\%$ reduction in average daily pain. Excellent correlation was seen in the response to the heat-capsaicin model where 14/16 pts experienced a $\geq 30\%$ reduction in the area of secondary hyperalgesia after smoking.

Results from this open-label pilot suggest an analgesic effect of smoked marijuana in HIV neuropathy as well as the experimental pain model. A 50 subject 7-day randomized placebo-controlled trial has been initiated in an attempt to confirm these preliminary findings.