

## Cannabinoid formulation benefits opioidrefractory pain

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(HealthDay) -- A novel cannabinoid formulation, nabiximols, is safe and effective for patients with advanced cancer and opioid-refractory pain, especially at a low-dose, according to a study published in the May issue of *The Journal of Pain*.

Russell K. Portenoy, M.D., of the Beth Israel Medical Center in New York City, and associates conducted a randomized, double-blind, placebo-controlled, graded-dose study of 263 patients with advanced cancer and opioid-refractory pain. Participants were randomly allocated to receive low-, medium-, or high-dose nabiximols or placebo. During five-weeks of treatment, average pain, worst pain, and sleep disruption were measured daily; quality of life and mood were also assessed.



The researchers found that, compared with placebo, the 30 percent responder rate primary analysis was not significant for nabiximols (P = 0.59). In a secondary continuous responder analysis of average daily pain, a significantly higher proportion of patients reported analgesia in the nabiximols group than placebo (P = 0.035), specifically for low-dose and medium-dose nabiximols (P = 0.008 and 0.039, respectively). Results were similar for mean average pain, mean worst pain, and mean sleep disruption in the low-dose group (P = 0.006, 0.011, and 0.003, respectively). There were no significant group differences seen in other questionnaires. Dose-related adverse events were seen, with only the high-dose group comparing unfavorably with placebo.

"Based on the results of this dose-ranging study, nabiximols in a manageable dose range may prove to offer benefits to a very ill population with refractory pain," the authors write. "Confirmatory studies are strongly warranted."

The study was funded by GW Pharmaceuticals, which produces nabiximols, and Otsuka.

**More information:** Abstract

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