

## Open-Label Study of Extended-Release Injectable Naltrexone (XR-NTX) in Healthcare Professionals With Opioid Dependence

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**Objective:** Opioid dependent healthcare professionals, who are at risk of relapse due to access to prescription opioids, may be required to undergo daily monitored oral naltrexone treatment. This pilot study evaluated the long-term safety, tolerability and efficacy of injectable, once-monthly, intramuscular XR-NTX in these opioid-dependent patients.

**Methods:** DSM-IV opioid-dependent healthcare professionals who had detoxified off all opioid agonists for  $\geq 2$  weeks (confirmed by negative urine drug screen and by negative naloxone challenge) were offered IM XR-NTX once-monthly for 24 months. Assessments included urine opioid drug tests, routine safety assessments, SF-36 Health Survey and the Opioid Craving Questionnaire.

**Results:** Of 49 patients screened, 38 (77.6%) were started on XR-NTX treatment. The majority (N=31; 81.6%) were female and most worked as nurses. To date, a Kaplan-Meier estimate shows that 50% of patients had been retained in treatment at least 12 months. Three have had positive urine drug tests for opioids, 2 of which were in month 1; 2 of these patients discontinued, and 1 patient continued in the study with negative opioids on all subsequent urine tests. There was a 46.3% reduction, from baseline to month 12, in the mean opioid craving score. On the SF-36, in which normative scores are = 50, the mean SF-36 Mental Component Score improved from baseline (33.7) to month 12 (44.7), and mean SF-36 Physical Component Scores were normative both at baseline (53.4) and month 12 (51.5). The mean Treatment Satisfaction Score was 90.7 (max = 100) at 12 months. At 1-year, discontinuations were due to an adverse event in 17%, and for other reasons in 30%. Adverse events were mild-to-moderate in intensity, with the most common events being injection site pain (39.5%), nausea (36.8%), anxiety (26.3%), and headache (23.7%). No patients died, overdosed or discontinued due to severe adverse events. Limitations include small sample size, open design and the unique population.

**Conclusions:** These results in at-risk healthcare professionals indicate that long-term XR-NTX was associated with good retention, with no new safety concerns and high rates of opioid negative urines, reduction in opioid craving, and improvement in mental health functional quality of life.

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