Injectable extended-release naltrexone (XR-NTX) for opioid dependence: long-term safety and effectiveness

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Study Overview and Objectives

This is a one-year open label study that followed a 6-month randomized, double-blind, placebo-controlled trial of 250 patients, comparing injections given every 28 days of extended-release naltrexone (XR-NTX) and counseling, vs. placebo and counseling for patients with opioid dependence. Patients receiving XR-NTX in the first 6-month phase were allowed to continue receiving the medication in the subsequent open-label phase. Patients receiving the placebo were allowed to switch to XR-NTX treatment during this open-label extension latter. All patients were provided counseling throughout both phases of the study. Patients had been using heroin for an average of 10 years at baseline (before the initial 6-month phase); approximately 88% were hepatitis C positive and nearly half were HIV positive. The purpose of this one-year, long term extension study was to assess the durability of improvements seen in the 6-month double-blind study, patient retention and safety over one year.

Results

- Nearly two thirds (62.3%) of patients continued treatment during the open-label extension phase and completed the full 12 months of treatment with XR-NTX.
- Half of the patients (50.9%) were abstinent (as determined by urine testing) from opioids at all assessments during the one-year extension phase.
- Across the one-year open-label phase, the percentage of opioid-free days was, on average, 83.4%.
- As reported as a secondary end-point in the double-blind phase, patients treated with XR-NTX reported significant reductions in craving for opioids which remained low during the one-year extension phase. Patients who were switched to XR-NTX in the extension phase also reported reductions in craving over time in the extension phase.
- No new safety concerns were observed during the 12-month extension phase.

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