A randomized, double-blind, placebo-cont... [Drug Alcohol...
A randomized, double-blind, placebo-controlled safety study of high-dose dextromethorphan in methadone-maintained male inpatients.

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Abstract

The NMDA antagonist dextromethorphan hydrobromide (DM) may be useful in the treatment of opioid dependence, particularly as a means of reducing tolerance to methadone during replacement therapy. As a prelude to clinical efficacy studies, a randomized, double-blind, placebo-controlled study examined the safety of DM in combination with methadone in inpatient, opiate-dependent volunteers. Male participants received daily methadone (50-70 mg/day) and either DM (n=10) or placebo (n=5) during the 12-day active medication phase of the study. DM participants received doses of 120, 240, and 480 mg/day in increasing order (4 days each). DM at high doses caused mild elevations of heart rate, blood pressure, temperature, and plasma bromide. However, none of these effects was clinically significant. DM caused no significant changes in respiration, pupil diameter, or subjective drug effects measured by standard scales. Participants in the DM group reported many more adverse events than did subjects on placebo (173 vs. 21), but these effects were not clinically serious. The most commonly reported side effects were sleepiness and drowsiness. Several participants reported intoxicating effects at the highest dose. Overall, DM was well-tolerated by the methadone-maintained opiate-dependent subjects studied here. These results support the further exploration of DM as an adjunct medication during methadone replacement therapy.

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