

## Long-acting treatment for opioid addiction reduced risk of relapse

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In a multicenter, randomized clinical trial, exprisoners who received six monthly injections of naltrexone—a long-acting medication that blocks opioid receptors in the brain—were significantly less all patients. Naltrexone, an opioid receptor blocker, likely to resume opioid use than those who received counseling and referrals to community treatment centers without naltrexone.

The study was published online today in New England Journal of Medicine.

The collaborative clinical trial included more than 300 men and women with opioid addiction who were treated at five study sites: University of Pennsylvania (Philadelphia), NYU Langone Medical Center Center (New York), Rhode Island Hospital and Brown University (Providence), Columbia University Medical Center (CUMC) (New York), and Friends Research Institute (Baltimore). Of the study participants who received counseling and referrals, 64 percent relapsed within six months, versus 43 percent of those treated with long-acting <u>naltrexone</u>. Although some of the participants in the naltrexone group relapsed, they used significantly less heroin and other opioids than those in the control group. In addition, there were no overdoses in the treatment group, compared with five overdoses in the control group.

One year after the initial study period, the control group had two additional overdoses, versus none in the naltrexone group.

Opioid addiction has become a public health crisis in the United States. According to the Centers for Disease Control and Prevention, drug overdoses, largely from opioids, killed more people than automobile accidents in 2013. Even as opioid addiction surges in the general population, it remains disproportionately high in the U.S. criminal justice system populations.

Two opioid substitution strategies, methadone maintenance and buprenorphine maintenance, are

effective in reducing relapse and overdose risk among opioid dependent individuals. But these medications are neither acceptable nor effective for uses a different mechanism, and thus expands available treatment options for people who are dependent on opioids.

"Dependence on opioids, including heroin and prescription painkillers, is a medical disease that has become increasingly pervasive throughout our urban, suburban, and rural areas and across all socioeconomic groups," said Edward V. Nunes, MD, Professor of Psychiatry at CUMC and a coauthor of the study. "It is hard to underestimate how deadly and devastating this disease is. It is a top killer of young people. Having another medication that is capable of reducing the risk of relapse and preventing overdoses is critical in the fight against opioid dependence."

All of the participants were encouraged to seek community-based treatment, regardless of treatment group, for another year following the initial six-month study period. Community-based treatment often includes counseling and daily treatment with methadone or suboxone, medications that prevent withdrawal symptoms by activating opioid receptors.

"Medications like methadone and buprenorphine have proved essential to the treatment of opioid dependence," noted Dr. Nunes. "But people with opioid dependence are better served by having a range of options to prevent relapse and reduce the risk of death from overdose. Naltrexone injections offer another effective therapeutic option for people struggling with opioid addiction in a variety of settings."

Extended-release naltrexone is the most recently FDA-approved product for the treatment of opiate addiction, and the only labeled for prevention of relapse. A daily, oral form of naltrexone has been



on the market since 1994 - but adherence to daily pill-taking was often poor. Extended-release naltrexone, approved by the FDA in 2010, requires only one monthly injection. This circumvents problems with adherence to daily pill-taking, and is a more viable treatment option.

The study is titled, "Extended-Release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders."

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