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NIDA Launches First Large-Scale National Study to Treat Addiction to Prescription Pain Medications

Researchers funded by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, are launching the first large-scale national study evaluating a treatment for addiction to prescription opioid analgesics (i.e., painkillers) such as Vicodin and OxyContin. NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) is conducting the multi-site study, known as the Prescription Opiate Addiction Treatment Study (POATS).

The study is a response to the growing national problem of prescription drug abuse in this country. According to the 2005 National Survey on Drug Use and Health, the incidence of new nonmedical users of pain relievers is now at 2.2 million Americans aged 12 and older, surpassing the number of new marijuana abusers (2.1 million). In 2005, more than six million Americans reported current (in the past month) nonmedical use of prescription drugs-more than the number abusing cocaine, heroin, hallucinogens, and inhalants, combined.

"The abuse of prescription opiates continues to be unacceptably high, producing steep increases in emergency room admissions," said NIH Director Dr. Elias A. Zerhouni. "This trial is part of our ongoing commitment to develop better treatment approaches for drug abuse and addiction, so devastating to millions of Americans and their families. "

The study will test the effectiveness of buprenorphine/naloxone tablets, marketed as Suboxone(r), along with different models of drug counseling in patients addicted to prescription opioids. Buprenorphine works by acting on the brain's own opiate receptors-targets for heroin, morphine, and prescription opioids-relieving drug cravings without prompting the same intense high or dangerous side effects. When combined with naloxone, buprenorphine's abuse potential is further limited, since those who try to inject it to get high experience severe withdrawal symptoms, while no adverse effects occur when it is taken orally, as prescribed. This medication has been approved for prescribing by specially trained physicians in office-based settings, greatly expanding the treatment options available for opiate addiction.

The study, which seeks to enroll 648 participants, will be carried out at 11 sites across the country. Participants will include people who take prescription drugs for chronic pain and have become addicted to them, as well as those who abuse painkillers for nonmedical reasons, including to get

"high." Several of the study sites are located in rural areas experiencing high rates of abuse of prescription pain medications, particularly OxyContin.

"This study is important because most of the research to date has been done on treatment for those addicted to heroin not prescription pain medications," said [Roger Weiss, MD](#), clinical director of [McLean Hospital's Alcohol and Drug Abuse Treatment Center](#) and lead investigator for the study. "It also isn't clear whether people who started taking these medications for legitimate reasons will respond to the same treatment in the same way as those who use pain medications solely on an illicit basis."

"Opioid analgesics were designed to help people in pain, and we want to be sure that those who require them for legitimate reasons can continue to effectively manage their pain," said NIDA Director Dr. Nora D. Volkow. "However, we must also recognize the risk of addiction to pain medications and develop treatments for those who become addicted to them. This trial is an important first step in reaching that goal."

Subjects enrolled in this study will be treated with Suboxone(r) for one month at the outset. They will then be stabilized and the dose tapered off as part of a detoxification process. If they remain abstinent for two months, they will complete the study. If they relapse and begin abusing prescription opiates again, they may be eligible to go back on the medication for three more months, taper off during a fourth month, and followed for two months.

In addition, to compare the effectiveness of different behavioral therapies in conjunction with the medication, half the subjects will be enrolled in an intensive individualized drug counseling program when they get their prescriptions. The other half will receive a brief drug counseling session from their doctors.

For more information about the study, go to: <http://www.drugabuse.gov/CTN/protocol/0030.html>

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The National Institute on Drug Abuse is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. The Institute carries out a large variety of programs to ensure the rapid dissemination of research information and its implementation in policy and practice. Fact sheets on the health effects of drugs of abuse and information on NIDA research and other activities can be found on the NIDA home page at www.drugabuse.gov.

The National Institutes of Health (NIH)-The Nation's Medical Research Agency-includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary Federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov/>.

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