

## NIAAA Study Shows Varenicline Reduces Alcohol Consumption

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Smoking-cessation drug varenicline showed promise as a treatment for alcohol dependence, according to a study by scientists at the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

The medication significantly reduced craving and alcohol consumption, according to the study, which was published online in the *Journal of Addiction Medicine*.

"Drinking and smoking often co-occur, and given their genetic and neurochemical similarities, it is perhaps unsurprising that a smoking cessation treatment might serve to treat alcohol problems," said lead author Raye Z. Litten, Ph.D., associate director of the NIAAA Division of Treatment and Recovery Research.

"Our study is the first multisite clinical trial to test the effectiveness and safety of varenicline in a population of smokers and nonsmokers with alcohol dependence," said Litten.

"This is an encouraging development in our effort to expand and improve treatment options for people with alcohol dependence," said Kenneth R. Warren, Ph.D., NIAAA acting director. "Current medications for alcohol dependence are effective for some, but not all, patients," said Warren in announcing the study results June 3. "New medications are needed to provide effective therapy to a broader spectrum of alcohol dependent individuals."

Varenicline partially stimulates receptors for nicotinic acetylcholine, a substance that is implicated in both nicotine and alcohol disorders.

In addition, early animal studies showed that varenicline decreases alcohol consumption.

"We don't know exactly how the nicotinic receptors are working," said Litten. "We do know that there seems to be a relationship between drinking and smoking."

The reward system may be involved, because the nicotinic receptors can affect dopamine release,

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he said. He noted that researchers still don't understand the mechanism responsible for alcohol addiction.

Litten and colleagues worked with NIAAA's Clinical Investigations Group, a multi-center team of researchers at Boston Medical Center; the University of Virginia, Charlottesville; Dartmouth University, Hanover, N.H.; the University of Pennsylvania, Philadelphia; and the Johns Hopkins University School of Medicine, Baltimore.

The researchers randomized 200 alcohol-dependent adults to receive 2 milligrams of varenicline or placebo each day for 13 weeks.

Study participants had reported drinking an average of at least 28 drinks per week for females or 35 drinks per week for males prior to the study.

The percentage of heavy drinking days decreased almost 22 percent in the varenicline group, compared with placebo. Varenicline also significantly reduced craving for alcohol.

These effects were comparable to those of naltrexone and acamprosate, two medications already approved for the treatment of alcohol dependence.

*No one with depression was allowed to participate in the NIAAA study, Litten told ADAW. Marketed under the trade name Chantix, varenicline was approved in 2006 for smoking cessation. Three years later, Chantix was given a black box warning by the Food and Drug Administration because of a risk of suicidal behavior when prescribed for psychiatric conditions (see ADAW, July 13, 2009). In November 2011, PLoS ONE published a study that compared varenicline retrospectively to other smoking-cessation treatments, and found that 90 percent of all suicides related to smoking-cessation drugs since 1998 implicated varenicline (see ADAW, November 7, 2011). The PLoS ONE study also found that varenicline was eight times more likely to result in a reported case of suicidal behavior or depression than nicotine-replacement medications.*