

# Cincinnati researchers conducting clinical trial of cocaine vaccine

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Researchers at the University of Cincinnati are conducting a clinical trial for a vaccine designed to treat cocaine addiction by preventing the drug from entering the brain, thus reducing its pleasurable effects.

Participants are being accepted for the study, a phase 2 clinical trial of the cocaine vaccine TA-CD (Therapy for Addiction-Cocaine Dependence). Phase 2 clinical trials are performed on larger groups after the initial safety of the study drug has been confirmed in phase 1 trials.

The study is being conducted at the Cincinnati Department of Veterans Affairs Medical Center in Corryville, but non-veterans are welcome to participate. The vaccine, whose patent is owned by the international private equity firm Celtic Pharma, is being provided to the VA Cooperative Studies Program via the National Institute on Drug Abuse, part of the National Institutes of Health.

Cocaine is a strong [central nervous system](#) stimulant and is highly addictive. According to the 2008 National Survey on Drug Use and Health, about 1.9 million Americans had used cocaine within the past month.

Scientists began developing the cocaine vaccine in 1997 after an article in Nature Medicine by Barbara Fox, PhD, hypothesized that vaccinating cocaine-addicted individuals against cocaine would likely be an effective way of treating the disorder.

Eugene Somoza, MD, PhD, a professor in UC's department of psychiatry and [behavioral neuroscience](#), says psychosocial treatment such as talk therapy is the current standard of care for cocaine-dependent patients.

"There are currently no Food and Drug Administration-approved therapies for [cocaine addiction](#)," says Somoza, who also noted that the study is important because of its vaccine-based approach and because it is synergistic with other treatments being studied that involve interventions targeting structures within the brain.

The study will test the efficacy of the vaccine versus a placebo with healthy cocaine-dependent volunteers over a period of 18 weeks, with a total of 300 patients participating at six sites. The lead investigator is Thomas Kosten, MD, of Baylor College of Medicine in Houston. Somoza is the principal investigator at the Cincinnati site.

Somoza notes that traditional immunotherapy targets involve complex molecules considered foreign by the body's [immune system](#), which develops specific antibodies against them. Cocaine is a simple molecule, and can only trigger the immune system by attaching to a complex molecule. When this happens, the immune system produces antibodies against it just as it does when viral or bacterial proteins enter the body.

As a result, when vaccinated patients use cocaine and its molecules reach the bloodstream, they are immediately sequestered by the antibodies—which hold on tightly to them, thus preventing them from entering the brain where they produce their deleterious effects.

"Addiction is dependent on how quickly the substance gets to the brain," Somoza says. "So by slowing down or stopping the process, it would be possible to decrease the pleasurable effect individuals get from cocaine."

Cocaine, as opposed to alcohol, opiates or benzodiazepines (such as Valium), does not usually produce severe withdrawal symptoms, according to Somoza. Thus, cocaine-dependent individuals are not compelled to take it every day and may choose to take it at convenient times, such as weekends.

This makes it significantly more difficult to determine whether or not addicted individuals have used cocaine on any given day, thus making the design of cocaine clinical trials more complicated than clinical trials on other addictive agents. For this reason, study participants will be required to come to the clinic three times a week. Participants may be compensated for time and travel.

Somoza's research team, co-directed by Theresa Winhusen, PhD, is the Cincinnati Addiction Research Center (CinARC). It has been conducting clinical trials for the past 15 years in an effort to develop new pharmacological and psychosocial treatments for addiction, now recognized as chronic relapsing brain disorder.

Somoza reports no conflicts of interest with the current trial.

Provided by University of Cincinnati

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