Varenicline for Comorbid Tobacco and Cannabis Use in Veterans

NCT05294263

August 30, 2023

Subject's Name: **Date:**

Principal Investigator: Dr. McRae-Clark

Study Title:
Varenicline for the Treatment of Cannabis and Tobacco Use Disorders in Veterans

SUMMARY:
You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate the safety and effectiveness of varenicline (sometimes known as Chantix) compared to placebo (an inactive substance) to reduce cannabis and tobacco/nicotine use in Veterans.

If you agree to participate, you will undergo a screening process which includes psychiatric and substance use assessments, a medical history and a physical exam. If you are eligible to continue, you will be randomly assigned to receive either varenicline or placebo. You will have a 50:50 chance of being on varenicline (like the flip of a coin). Neither you nor your study doctor will know what group you are in. You will take the study medication twice a day for 12 weeks and will have study visits once a week for those 12 weeks, with follow up visits two and four weeks after. You will be asked to complete questionnaires about substance use at each visit. Urine and breath will be sampled weekly. Cognitive testing will be done at the beginning and end of treatment.

There are risks to the study drug that are described in this document. An example of a risk is nausea (upset stomach). If you are randomized to placebo, you will go without treatment for your condition for 12 weeks. Also with randomization, neither you nor your doctor will decide to what group you are assigned. If you have a strong opinion about what treatment you receive or would like your doctor to decide what treatment you receive, you should not participate in this study.

It is unknown if varenicline will help your condition, however you will be followed closely with weekly visits, and you can stop participating in the study at any time. It is possible that your symptoms will improve, but that cannot be guaranteed. You do not have to participate in this study to have your condition treated. Alternative treatments include special counseling and other therapies.

If you are interested in learning more about this study, please continue to read below.

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PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study designed to evaluate the effects of a medication (varenicline) to help Veterans quit using cannabis and tobacco/nicotine.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. To confirm your understanding, you will be asked to complete a consent quiz before signing this form.

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You are being asked to participate in this study because you use tobacco/nicotine and cannabis regularly. The study is sponsored by the VA Clinical Science Research and Development. The investigator in charge of this study at the Ralph H. Johnson VA Medical Center is Aimee McRae-Clark, PharmD. Approximately 138 people will take part in the study.

PROCEDURES:

If you agree to be in this study, you will first be evaluated and the results of the evaluation must meet entrance requirements. This evaluation will include psychiatric interviews, an assessment of your alcohol and drug use, and a medical history and physical exam. You will be asked to fill out several forms dealing with how often and why you use cannabis and tobacco/nicotine, your mood symptoms, and sleep quality. You will be asked to provide a urine sample to test for drugs of abuse and a breath sample to measure carbon monoxide.

If you are female and of child-bearing potential, you will have a pregnancy test prior to urine drug screening. If you are capable of becoming pregnant, you must be using a medically approved method of birth control (such as contraceptive pills, diaphragms, or other forms of barrier contraceptives) and you must continue to do so during the course of the study. Should you become pregnant during the study you must immediately contact your study doctor and discontinue treatment since the risk to your baby due to varenicline is unknown.

If you meet all entrance requirements, you will come to the clinic for a randomization visit. At this visit you will be asked to provide a urine sample to test for drugs of abuse and nicotine and a breath sample to measure carbon monoxide. You will complete cognitive testing to measure things like memory and attention. You will also complete assessments regarding cannabis and tobacco/nicotine use and mood, and you will receive study medication, either varenicline or placebo (a capsule that does not contain any active medication). Neither you nor the study staff will know which medication you are taking as both varenicline and placebo will be given as capsules identical in appearance. You will be randomly assigned to receive either varenicline or placebo. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice regarding to which group you are assigned. The medication will be provided at the standard recommended dose for smoking cessation of 0.5mg daily for three days, then 0.5mg twice daily for four days, and then 1mg twice daily for the remainder of the twelve-week treatment period.

You will be required to take your medication twice daily while enrolled in this study. You are asked to take one capsule at 8:00AM each morning and the other at 8:00PM each evening.

Subject's Name: **Date:**

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You will have weekly study visits for eleven weeks. At these visits, you may be asked to fill out forms and answer specific questions concerning your substance use, mood symptoms, and your feelings in general, either in clinic or via survey link. Your urine will be tested at each visit to check for drugs of abuse and nicotine, and you will provide a breath sample. If you are female, you will be screened for pregnancy monthly. You will be asked about study medication compliance and side effects, use of any new medications, and encouraged to abstain from cannabis and tobacco/nicotine use. In some circumstances, these visits may be conducted remotely via a telehealth platform. At your final study visit, you will repeat the cognitive testing that was done at randomization.
You will be required to complete follow-up visits approximately two weeks and four weeks after you finish study procedures.

We may ask you to identify an individual who can be contacted to help locate you if needed. A family member or a significant other/spouse is preferred. You will need to sign a release of information form to allow the study team to contact the individual.

You may withdraw your consent in writing, and you may and discontinue participation at any time. Discontinuation will in no way jeopardize your ability to receive treatment at this Institution now or in the future. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

C. DURATION:

Participation in this study involves approximately 15 visits over a period of about three months. The initial screening visit will take about 3 hours. The rest of the visits will take approximately 30-60 minutes each.

D. RISKS/DISCOMFORTS:

Participation in this study may involve risks. There may be risks and side effects that are not known at this time. Possible risks from study participation include:

Subject's Name: **Date:**

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Risks associated with varenicline: The most commonly observed side effects associated with varenicline treatment (incidence > 5% and at least twice the rate of placebo) are nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, and vomiting. Neuropsychiatric adverse events (such as changes in mood, anxiety, and increased aggression) have occurred in patients without and with pre-existing psychiatric disease; some patients experience worsening of their psychiatric illnesses. These events may be worsened with alcohol use. In individuals with major depressive disorder and other psychiatric disorders, medications like varenicline may increase suicidal thoughts and behavior. Watch for these changes and inform the study staff immediately if you notice new or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe. You should also use caution driving or operating machinery or engaging in other potentially hazardous activities until you know how the study medication affects you.

Risks associated with screening/assessment: The interviews that you will undergo at screening involve no specific risks or discomforts beyond those of a standard clinical interview situation, such as feeling upset at the review of your psychiatric status, boredom, or fatigue. If a question makes you feel uncomfortable you may refuse to answer it.

Risk of loss of confidentiality: There is a risk of a loss of confidentiality as a result of participation in this study. Information about you, as well as your image, will be kept in password-protected databases and computers or a locked research clinic area, and will only be accessible by the principal investigator and the research staff. In order to ensure confidentiality, all participant information (questionnaires and identifying information) will be identified only by your name and/or a code number and kept under lock and key and in password-protected databases.

Additional risks: You will be assigned to treatment by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment or other available treatment. If you are in the group that receives placebo, you will not receive active medication.

Unknown risks: There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect. Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your healthcare providers if you have any questions about the risks of usual care."

Risk of pregnancy and drug testing: If you are a female of childbearing potential, you will receive a pregnancy test, and if pregnant, you will not be allowed to participate in the study. Your urine will be screened for the presence of cannabis and other potentially abused or illegal drugs. These results will not be part of your medical

record but will be kept in research records maintained by the investigator. Every effort will be made to protect the confidential nature of this information. However, there may be circumstances under which the investigator may release this information. If you are pregnant or become pregnant and test positive for illegal drugs, the SC Department of Social Services (DSS) may be notified. You could be at risk of going to jail or losing custody of your children.

E. MEDICAL RECORDS:

If you are a Ralph H. Johnson VA Medical Center patient, you have a VA medical record. If you have never been a Ralph H. Johnson VA Medical Center patient, a VA medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your VA medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. BENEFITS:

You may receive a medication that may be effective in reducing your cannabis and cigarette use. Of course, this cannot be guaranteed or promised. The results of this study may also benefit other patients who might later be treated with the same medicine.

G. COSTS:

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these copayments for VA care and medications that are not part of this study.

H. PAYMENT TO PARTICIPANTS:

In return for your time and effort, you will receive $50 for completing the screening visits and $50 for all weekly clinic visits and the follow up visits. Therefore, if you complete all scheduled study visits, you can earn up to $750. Payments will be made with electronic funds transfer or with a Debit Mastercard. The IRS requires a tax form be filed if your compensation exceeds $600.00/year. However, if the payment for participation will be made through Austin Financial Services Center, it may generate IRS Form 1099 automatically, regardless of amount.

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I. ALTERNATIVES:

There are alternative treatments for cannabis and tobacco/nicotine use. These include special counseling and other therapies (such as twelve step groups to decrease substance use and medication for smoking cessation). You may also choose not to participate.

J. DATA SHARING:

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS:

You will not receive a report of the study's findings. If there are significant new findings during the course of the study, you will be notified.

L. CLINICAL TRIAL REGISTRY DATABANK:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

CONSENT

Your privacy is very important to us and the researchers will make every effort to protect it. Results of this research will be used for the purposes described in this study. These results may be published, but you will not be identified.

The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. There are times when we may have to show your records to other people from Federal agencies that oversee our research such as the Department of Health and Human Service's Office of Human Research Protections (OHRP), the Food and Drug Administration (for FDA regulated research only), the Government Accountability Office (GAO), the VA Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), our

local VA Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Also, all records in South Carolina are subject to subpoena by a court of law. Any information shared with these outside groups may no longer be protected under federal law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Ralph H. Johnson VA Medical Center. Financial compensation is not available for such things as lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteer's Statement

A research study doctor or coordinator has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact: Dr. McRae-Clark at (843) 792-5216.

If I have questions about my rights as a study participant, or I want to make sure this is a valid VA study, I may contact the Medical University of South Carolina's Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. I may call the MUSC IRB (843) 792-4148, or the Ralph H. Johnson VA Medical Center's Research Compliance Officer at (843) 789-7399, if I have questions, complaints or concerns about the study or if I would like to obtain information or offer input.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

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I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date