

Official title of study: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia

NCT number: NCT03838484

Date of document: 10/23/2019

VUMC Institutional Review Board
Informed Consent Document for Research

1

Study Title: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia
Version Date: 02
PI: 10/23/2019
Alan Lewis, MD, PhD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?

You are being asked to take part in this research study because you are an adult diagnosed with schizophrenia or schizoaffective disorder or are a healthy control subject. The purpose of this study is to test whether nicotine, a drug that activates receptors called nicotinic acetylcholine receptors in the brain, improves your ability to make or withhold responses to faces that are either emotionally neutral or emotionally negative. This study will also test whether the drug affects your brain activity while you are making or withholding responses using electroencephalography. Previous studies in people with schizophrenia have shown that more errors in response to negative emotional cues are related to greater likelihood of impulsive aggressive behavior. Therefore, the aim of this study is to determine whether nicotine might be a new strategy to reduce aggressive behavior. We would like to enroll about 30 participants with schizophrenia and 30 healthy controls in this study at Vanderbilt. The main risks of this study relate to temporary uncomfortable effects of nicotine.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Health Screen Risks: During the health screen, some questions may deal with personal or emotional matters. These matters may be stressful or upsetting to think about. You may refuse to answer any questions that make you too uncomfortable.

To measure your heart rate and rhythm an electrocardiogram (ECG) will be done. This is a test that records the electrical activity of the heart. You will be asked to lie down and sticky patches will be fixed to your chest. You will be asked to lie still. The sticky pads used for the ECG may cause skin irritation.

EEG risks: There is risk of mild discomfort to the scalp while wearing the EEG headcap.

VUMC Institutional Review Board
Informed Consent Document for Research

2

Study Title: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia
Version Date: 02
PI: 10/23/2019
Alan Lewis, MD, PhD

Nicotine may commonly result in side effects that are uncomfortable but temporary. Specifically, nicotine, like caffeine, can make some people feel stimulated. By this, you may notice that your heart is beating faster, or that you feel slightly anxious. You may feel mildly nauseous or lightheaded. Most individuals are not overly bothered by these symptoms, however, if these symptoms are intolerable, the patch will be removed from your skin and symptoms will resolve soon thereafter.

Medication skin patches may also lead to mild skin irritation. Because the duration of wear is very short, this is unlikely, and any irritation will resolve after patch removal.

Previous studies using single-dose nicotine for a short period have demonstrated no evidence for inciting nicotine addiction or withdrawal.

Because there are risks associated with nicotine on fetuses or on young children who are breastfed by an individual exposed nicotine, you will not be permitted to take part in the study if you are pregnant, at risk of becoming pregnant, or are breastfeeding.

Risks that are not known:

Because this use of transdermal nicotine is “off-label”, meaning use of nicotine in this study is not an approved indication by the U.S. Food and Drug Administration (FDA), there may be risks that we do not know about at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: This study is designed to test a biological mechanism that may ultimately lead to new treatments for impulsivity and aggressive behavior. Therefore, participation in this study may, in time, benefit both individuals with schizophrenia as well as society at large.

Payments for your time spent taking part in this study or expenses:

You will be provided \$25 for completion of the screening visit, which will be provided at the end of this visit regardless of your decision to enroll in the study. You will receive an additional \$100 at the completion of the second testing visit. You will not receive any payment if you only complete the first testing visit without completing the second testing visit.

Your travel costs will be reimbursed. If driving, mileage will be reimbursed at the current Internal Revenue Service (IRS) rate for business purposes. If arriving by bus, you will be reimbursed upon provision of proper receipts. Taxi fare (including Uber or Lyft) will not be reimbursed.

Study Title: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia
Version Date: 02
PI: 10/23/2019
Alan Lewis, MD, PhD

As an identifier for internal auditing purposes, your social security number is needed because you are receiving payment for taking part in this study. Vanderbilt University Medical Center is required to tell the IRS of any payments to you as a subject in research studies in a given calendar year totaling \$600 or more. If that occurs, you will receive a 1099 form at the end of the year. No information identifying why you received payment is given to the Hospital's accounting department or the government. This information is kept strictly confidential.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the National Institute of Mental Health to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt National Institute of Mental Health to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Alan Lewis, MD, PhD at 615-875-4027.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

Dr. Lewis can remove you from the study at any time if it is in your best interest or the best interest of the study. Potential reasons can include development of adverse events from the study drug or study procedure that might lead to concerns about your safety, as well as difficulty with following study instructions or poor compliance. Dr. Lewis will tell you why if you are removed from the study without your permission. If there are any new significant findings that may affect your desire to take part in this study, you will be told right away.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

VUMC Institutional Review Board
Informed Consent Document for Research

4

Study Title: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia
Version Date: 02
PI: 10/23/2019
Alan Lewis, MD, PhD

Clinical Trials Registry:

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

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Electronic databases containing identifiable subject information will be password encoded. Written information containing subject identifiers (informed consent, payment forms, etc.) will be stored in locked file cabinets in offices within the Department of Psychiatry. Subjects will be assigned an alphanumeric code that will be used to label all research data including all questionnaires.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:

Your individual study results will not be shared with you. The final results of the study will be made available through www.clinicaltrials.gov and potentially through publication in the scientific literature.

Study Title: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia
Version Date: 02
PI: 10/23/2019
Alan Lewis, MD, PhD

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

VUMC Institutional Review Board
Informed Consent Document for Research

6

Study Title: Effects of transdermal nicotine on response inhibition to emotional cues in schizophrenia
Version Date: 02
PI: 10/23/2019
Alan Lewis, MD, PhD

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date

Signature of patient/volunteer

Consent obtained by:

Date

Signature

Printed Name and Title

Time: _____