

UT Austin IRB Approved
Study Number: 2016-09-0152
Approved: 11/29/2018

Name of Funding Agency: National Institute on Aging

Consent for Participation in Research

Title: Nighttime Agitation and Restless Legs Syndrome in People with Alzheimer's Disease

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study to see if treatment of your restlessness at night, using a medication called gabapentin enacarbil, can help older adults sleep better and have less nighttime agitation.

The purpose of this study is find out if a sleep disorder called restless legs syndrome may be causing nighttime sleep disturbances and nighttime agitation behaviors such as confusion or wandering. This research will find out if treatment of restless legs syndrome with a Food and Drug Administration approved medication, gabapentin enacarbil, reduces or eliminates nighttime agitation behaviors, improves sleep, and reduces the need for antipsychotic medications.

A description of this study 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.

What will you be asked to do?

If you agree to participate in this study, you will

- Provide information such as your age, medical history, nighttime behaviors, and medications that will be gathered from your chart, from the nursing staff, from your physician and from your primary caregiver (e.g., family member).
- Have your memory tested.
- Have several physical examinations.
- Be randomized (like the toss of a coin) to take a medication, gabapentin enacarbil, or a placebo (a look-alike but inactive tablet) once a day for 8 weeks.
- Be continuously observed by project staff at the beginning of the study, at 2 weeks, and at 8 weeks on 2 nights to find out if you are having any behaviors such as confusion or wandering. The observations will occur from 5-10 pm on the first night, from 10 pm to 7 am on the second night. If you agree, your behaviors may also be video recorded for training of the project staff and/or scoring of the behaviors by the project staff.
- Be observed for 20 minutes at the beginning of the study, for 20 minutes at 2 weeks, and for 20 minutes at 8 weeks to find out if your legs are restless. A video camera may be used for these observations.
- Wear a small watch-like device (accelerometer) on your wrist to measure your sleep, body movements, and position for 7 days and nights at the beginning of the study, for 7 days and nights 2 weeks later, and for 7 days and nights at the end of the study. (Optional)
- Wear ankle bands (RestEaZe™) on your right and left ankles to measure leg movements and body position during the 20-minute, 5-10pm, and 10pm to 7am observations at the beginning of the study and again 2 weeks later. (Optional)
- Have 2-3 teaspoons of blood drawn one or two times using aseptic technique by an experienced nurse for a blood count, blood iron levels, and kidney test, if you have not had the tests in the last 2 weeks. Aseptic technique includes sterile and/or disposable equipment (e.g., blood collection apparatus) and adherence to standard medical precautions.
- Have your medication orders and records checked for about 8 weeks after you finish taking the medication or placebo.

You will be involved in the study for about 18 weeks. The study will include approximately 136 participants.

This is a research study and, therefore, not intended to provide a medical or therapeutic diagnosis or treatment. The intervention provided in the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition.

What are the risks involved in this study?

This research may involve risks that are currently unforeseeable.

There is risk of loss of confidentiality. There is risk of bruising from the blood draw and skin abrasion from the ankle bands. You may feel distress because of your performance on the memory tests. You may feel distress and loss of privacy when you are observed at night.

Gabapentin enacarbil, is approved by the Food and Drug Administration.

You may experience side effects from taking gabapentin enacarbil or the placebo.

Gabapentin enacarbil may cause significant driving impairment. Persons on this drug should not drive or operate heavy machinery.

The most common risks with a 600-mg dose of gabapentin enacarbil and how often they occurred in other studies were sleepiness (20%), dizziness (13%), headache (12%), nausea (6%), and fatigue (6%).

Sleepiness was reported in 20% of patients treated with 600 mg gabapentin enacarbil versus 6% of patients receiving placebo.

Dizziness was reported in 13% of patients receiving gabapentin enacarbil compared to 4% of those receiving the placebo.

Suicidal thinking or behavior is also a risk. The estimated risk of suicidal thinking or behavior is 0.43% with gabapentin enacarbil and similar drugs, compared to 0.24% in patients given placebos.

Other less common risks are irritability, weight or appetite changes.

Alternative medications for nighttime agitation behaviors are primarily antipsychotics, and they are associated with falls, strokes, and death.

What are the possible benefits of this study?

The possible benefits of this study are:

- diagnosis of a treatable condition that causes discomfort, restless legs syndrome, using a new tool that is not currently available to doctors,
- if randomly assigned to the active medication group, a tailored treatment for nighttime agitation behaviors that may result in improved quality of sleep, less agitation, and less discomfort from restless legs syndrome,
- blood tests that may identify abnormalities or a change in blood iron levels and/or kidney function, and
- assessments by the study registered nurse that may result in early identification of health problems.

An additional benefit if you give permission, is that the study nurse will inform your physician in writing:

- that you are completing the research,
- that you have a restless legs syndrome diagnosis and any medications that you are taking that might aggravate the condition,
- an overall clinical assessment by the nurse of your response to treatment and of any study-related adverse events, and
- the date that the drug/placebo will be tapered and discontinued.

Participants in both groups will not be deprived of any current care.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. If you wish to withdraw from the study, we will ask if you are willing to continue having the study outcome measures collected. Withdrawal or refusing to participate will not affect your

relationship with The University of Texas at Austin (University) in anyway.

If you would like to participate please sign the consent form and return it to one of the project staff. You will receive a copy of this form.

What are the alternatives to participating in this research?

The alternative is to continue the care you are currently receiving.

Will there be any compensation?

If you complete the research you will receive a 1-hour social activity session provided by study staff, your favorite refreshments, and a framed certificate. The project staff will provide the social activities, and they will tailor the activities to your interests and preferences. Dr. Richards will send you and your legally authorized representative if you have one a thank you note.

You will not receive any type of payment for participating in this study.

What if you are injured because of the study?

Gabapentin enacarbil is approved for treatment of restless legs syndrome by the Food and Drug Administration. The University has no program or plan to provide treatment for research related injury or payment in the event of a medical problem. However, in the event of a research related injury, please notify Dr. Richards, principal investigator, at 703-946-3725.

How will your privacy and confidentiality be protected if you participate in this research study?

Your privacy and the confidentiality of your data will be protected. Data will be reported in aggregate form, and neither where you live nor you will be identifiable. All study materials will be secured on a password protected research server or stored in a locked office in a locked cabinet. Information linking your research identification number to your personally identifiable information will be kept separately.

The investigators and all the research staff participating in this study will have completed a course in the appropriate conduct of patient-oriented research and privacy regulations offered by the Institutional Review Boards of their respective Universities. All

future staff involved in the project will also be required to complete this course.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

If you choose to participate in this study, you may be chosen to be video recorded. Any video recordings will be stored securely and only the research team will have access to the recordings. Recordings will be kept for 5 years and then erased.

Can I voluntarily be removed from the trial?

The study investigators may decide to remove you from the trial without your consent if you experience serious adverse events that the study physician or your personal physician believe are associated with the study drug.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact Kathy Richards, PhD at 703-946-3725 or send an email to kricha@utexas.edu for any questions or if you feel that you have been harmed.

This study has been reviewed and approved by The University Institutional Review Board and the study number is 2016-09-0152.

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

Participation

If you agree to participate please give the signed form to one of the project staff or mail it to: Project Coordinator, Nighttime Agitation and Restless Legs Syndrome in People with Alzheimer's Disease, The University of Texas at Austin, School of Nursing, 1710 Red River, Austin, Texas 78712.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ I agree to be video recorded.
_____ I do not want to be video recorded.

_____ I agree to wear accelerometers.
_____ I do not want to wear accelerometers.

_____ I agree to wear RestEaZe™ ankle bands.
_____ I do not want to wear RestEaZe™ ankle bands.

_____ I agree to provide information on the results of this study to my doctor, Dr. _____.
_____ I do not want to provide information on the results of this study to my doctor.

Participant Printed Name

Participant Signature Date

Legally Authorized Representative Printed Name

Legally Authorized Representative Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

Print Name of Person obtaining consent

Signature of Person obtaining consent

Date