Official Title: Open label safety study of solriamfetol to promote wakefulness and improve cognition and quality of life in patients with primary gliomas

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Department/Section of *Department of Neurology and Internal Medicine, Section on Hematology and Oncology*

OPEN LABEL SAFETY STUDY OF SOLRIAMFETOL TO PROMOTE WAKEFULNESS AND IMPROVE COGNITION AND QUALITY OF LIFE IN PATIENTS WITH PRIMARY GLIOMAS – CCCWFU 98418

Informed Consent Form to Participate in Research

Roy Strowd, MD Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this study is to find out what effects (good and bad) a medicine called solriamfetol has on you. This is a new medication that helps patients feel more awake. You are invited to be in this study because you have a brain tumor and may have problems sleeping.

If you choose to participate in this study, three things will happen. First, we will ask you to keep a diary of your sleep for 7 days. You will write down things like when you go to sleep, when you wake up, and you will wear a watch that measures your sleep. Second, you will take a pill called solriamfetol. This pill is taken once a day every day. You will take up to three different doses of this pill. You will take a low dose for 7 days, then a slightly higher dose for 7 days, and then a slightly higher dose for 7 days. These three doses have been tolerated in other patients. We will ask you to keep a diary of your sleep during the study and will have you wear the watch to record how much you are sleeping. We will call you once a week to check on how things are going and monitor for side effects. After you have taken the three doses of the solriamfetol medication, we will see you in clinic for a visit. Third, you will then continue to take the solriamfetol pill (at the highest dose for you) for 6 straight weeks. At the end of the 6 weeks we will check to see how you are sleeping. "In person" visits may be conducted by telehealth (the provision of healthcare remotely by means of telecommunications technology by video or telephone).

Altogether, the treatment will last about 10 weeks. After that you will no longer take the study medication. We will call you or have you return to clinic 30 days after you stop the medication to see how you are doing and ask about side effects.

All research studies involve some risks. For this study, you should be aware that you may feel side effects to the solriamfetol pill. Side effects that have been experienced by patients in the past include headache, nausea, diarrhea, decreased appetite, anxiety, discomfort in the chest, muscle tightness, dry mouth, and problems sleeping. There is a possibility that you may benefit from participation in this study by having better sleep and feeling more awake.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include taking a different medication to help your sleep or getting a sleep study to test your sleep. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Roy Strowd, MD (Principal Investigator). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted] (daytime), [redacted] (alternative daytime), [redacted] (after hours), [redacted] (alternative after hours).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have a brain tumor and may have problems sleeping. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

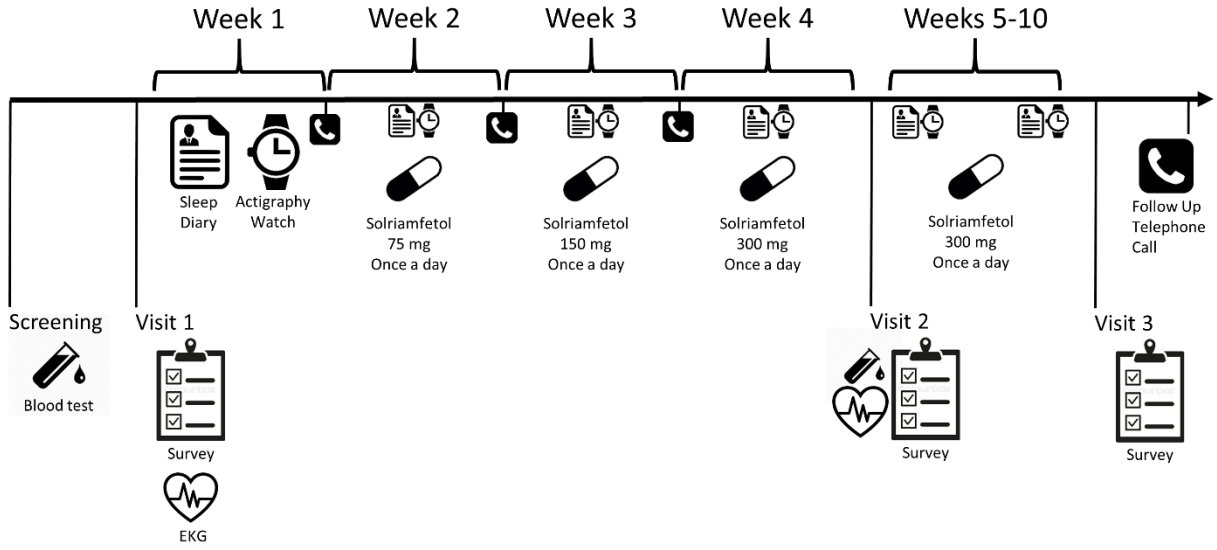
The purpose of this research study is to find out what effects (good and bad) solriamfetol has on you. Solriamfetol is a new pill that has been studied in patients with other conditions resulting in sleep disorders such as obstructive sleep apnea and narcolepsy. In these research studies, solriamfetol has been tolerated and has improved sleep. The goal of this research study is to see if this medication is safe and will improve sleep in patients with brain tumors.

Solriamfetol is an FDA approved drug. This means it has been approved by the U.S. Food and Drug Administration (FDA).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

36 people at one research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?



At your screening visit, you will complete a short survey and a blood draw to see if you are a candidate for the study. The survey will take approximately 5 minutes. For the blood draw, you will have two small tubes of blood (approximately 12 mL = 3 teaspoons) collected from a vein. This visit can be performed via telehealth. If telehealth is used, you will be expected to get the blood draw at a primary care office or lab near your home.

At your first visit, you will receive a physical exam, complete several surveys, and have a test of your heart rhythm called an electrocardiogram. For the electrocardiogram, small stickers will be placed on your chest and arms to measure your heart rhythm. The surveys will take approximately 60 minutes and include questions about your sleep, memory, fatigue, mood, and quality of life. This visit will be in-person.

During the first week (days 1-7) of the study, you will complete a daily sleep diary. To do this you will write down when you went to sleep, when you woke up, and other information about your sleeping. You will also wear a watch that measures the time that you go to sleep and wake up. At the end of this week you will receive a telephone call from our research team to see how you are doing. You will not need to come into clinic for a visit.

During the second, third, and fourth week (approximately days 8-29) of the study, you will take a pill called solriamfetol. This medication will be provided to you at the first study visit. You will take this pill once a day by mouth. You will write down when you take this pill into a diary. You will continue to record your sleep in the sleep diary and wear the watch that measures your sleep times. At the end of each week, you will receive a telephone call from our research team to see how you are doing. You will start by taking 75 mg of solriamfetol for the first week, then 150 mg of solriamfetol for the second week, then 300 mg of solriamfetol for the third week. These three doses have been used in other patients who have taken this medication. The study team will monitor any side effects that you have and if needed your dose may be changed.

At your second visit, you will receive a physical exam, blood draw, complete several surveys, and receive an electrocardiogram. For the blood draw, you will have two small tubes of blood (approximately 12 mL = 3 teaspoons) collected from a vein. The surveys will take approximately 30 minutes and include questions about your sleep, fatigue, mood, and quality of life. If determined by you and your doctor, this visit can be performed via telehealth. If telehealth is used, you will be expected to get the blood draw at a primary care office or lab near your home.

Over the next 6 weeks you will continue to take solriamfetol. You will take one of the solriamfetol doses that was well-tolerated. You will be told the dose of the medicine that you will take. The dose will not change during the 6 weeks. You will be asked to write down when you take this pill into a diary. You will record your sleep in the sleep diary and wear the watch that measures your sleep times during two of these 6 weeks.

At the third visit, you will receive a physical exam, blood draw, and complete several surveys. For the blood draw, you will have two small tubes of blood (approximately 12 mL = 3 teaspoons) collected from a vein. The surveys will take approximately 60 minutes and include questions about your sleep, memory, fatigue, mood, and quality of life. After this, you will not take any more of the solriamfetol medication. This visit will be in-person.

You will receive a telephone call approximately 30 days after this visit to see how you are doing.

The total amount of blood withdrawn during the study will be approximately 3 tablespoons (36 mL).

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

How Long Will I Be in the Study?

You will be in the study for about 14 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. We do not anticipate any serious consequences of sudden withdrawal from the study.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the drug we are studying include:

Common (approximately 5-20%):

- Headache (11-21%)
- Nausea (8-11%)
- Decreased appetite (5-11%)
- Cough and runny nose (called nasopharyngitis) (8%)
- Anxiety (6-7%)
- Diarrhea (5-6%)
- Dry mouth (5-7%)
- Insomnia (5-8%)
- Upper respiratory tract infection (5%)

Rare but potentially important (<1%):

- Abnormal heart rhythm called atrial fibrillation
- Heart attack
- Chest pain
- Stroke
- Blood clot in the lungs

Other potential side effects:

- Seizure

Privacy and Confidentiality
In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

Survey Questions
As part of this study, you will be asked questions about depression. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Blood Draws
You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

As part of this study, you will be asked questions about depression. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Reproductive Risks and other Issues to Participating in Research

Female subjects of childbearing potential who are sexually active and male subjects who are sexually active and have female partners of childbearing potential must agree to use a medically acceptable method of contraception with their partners during exposure to solriamfetol and for 30 days after the last dose of solriamfetol

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Contraceptive Measures for Males

Your participation in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for thirty (30) days afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: improvement in your sleep, memory, fatigue, mood or quality of life.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- Try a different medication for sleep
- Participate in a sleep study that will test whether you may have another reason for your poor sleep

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published

in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or for taking part in this study. Parking will be validated for study related visits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Jazz Pharmaceuticals, IncThe sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Strowd at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: age, type of brain tumor type, types and dosages of chemotherapy received, and other medical conditions.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Roy Strowd, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Roy Strowd, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://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.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study

at any time. This could be for your best medical interest, your condition has worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Roy Strowd, MD at [redacted] (daytime or after hours).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm