Effect of PDE5 Inhibition on Adipose Metabolism in Humans

Informed Consent Document

NCT04684589

Date of IRB Approval: 11/14/2024

Study Title: Effect of PDE5 Inhibition on Adipose Metabolism in Humans
Version Date: 07/24/2024
PI: Evan Brittain, MD, MSc

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.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of this study is to find out if a medication called tadalafil improves metabolism in individuals who are obese. In this study we will look at how tadalafil changes how fat uses energy. We will measure fat metabolism in two ways: 1) using magnetic resonance imaging (MRI) scans, and 2) collecting a small amount of fat from the abdominal area using a needle. This drug is approved by the Food and Drug Administration (FDA) for other conditions and is generally well tolerated. The most common side effects are headache, muscle aches, and heartburn.

Participation in this study will require 4 study visits over approximately 12 weeks. Two of the visits will be at least an hour and the other two will take 6-8 hours. Participants will undergo 2 MRI scans involving cooling of the skin, 2 DEXA scans, collection of 4 fat samples, several urine collections, and several blood draws. In addition to the study visits, participants will wear an activity tracker (Fitbit) and log their dietary intake several times using an online tool. Participants will the medication tadalafil for 12 weeks. Participants will be compensated.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are overweight and have no signs of heart disease.

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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.

It will take you approximately 14 weeks to complete this study. During this time we will ask you to come to a screening visit to determine if you are eligible to participate. If you are eligible and decide to consent, you will have study visits at baseline, 10 weeks, and 12 weeks. The baseline and 12 week visits will take approximately 6-8 hours. The 10 week visit will take at least an hour. You will receive phone calls approximately every 2 weeks to see how well you are tolerating the study medication and if you are having any problems taking the medicine daily. You will also be asked to complete a dietary intake survey (online) on two weekdays and one weekend day during weeks 1, 6, and 12, and wear an activity tracker (Fitbit) for the duration of the study. We will ask you to come to the Clinical Research Center (CRC) located on the Vanderbilt Campus in Medical Center North for each of your study visits. Your 10 week visit may take place in the Cardiovascular Research Room in the Preston Research Building. Details for each study visit are outlined below.

Screening Visit

This visit will last about 1 hour, and we ask that you present having fasted for at least 12 hours. First, we will tell you what will happen during the study and inform you about the risks and benefits of the study. We will also ask you about your medical history and confirm you qualify based on your height and weight. We will perform a blood draw of approximately 7.5 ml (1.5 tablespoons). You will be eligible if your body mass index is greater than 30 and you have no disqualifying health problems. You can ask questions about the study. You will then decide if you want to be in the study. If you decide to participate in the study, we will ask you to sign this form.

After consent, we will escort you to the Vanderbilt University Institute for Imaging Science (VUIIS), where the MRI scans will take place. We will ask you to lie in a "mock" scanner to make sure you will be comfortable during the study scans. A mock scanner that is no longer in use but is very similar to the scanner that will be used for the study visits. We will not take any pictures during the screening visit. We will also place on you the cooling blanket that will be used for the study visits. We will not perform any cooling during the screening visit. We simply want to make sure you will be comfortable with the equipment we will use on the study days.

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Finally, we will ask you to complete a safety screening form for magnetic resonance imaging (MRI). This will take 5-10 minutes.

Baseline and Week 12 Testing:
Baseline testing will take approximately 6-8 hours. This visit will involve the following procedures, described in detail below:

- Blood work (5 minutes)
- Urine pregnancy test for female participants (2 minutes)
- Fat aspiration x 2 (30 minutes)
- MRI scan with cooling protocol (90-120 minutes
- DEXA body composition testing (15 minutes)

At your baseline visit, you will be randomized (i.e. assigned by chance, like flipping a coin) to either the tadalafil or placebo arm of the study. This study is double-blinded, so neither you nor study personnel will know if you are taking tadalafil or the placebo pill.

Diet/Activity Habits before Baseline and Week 12 Testing Sessions: For your safety and to make sure that the best data possible will be collected, we ask that you:
DO NOT eat or drink anything (other than water) for 10-12 hours prior to your arrival for testing
DO NOT take any non-prescription medications during the 48 hours prior to testing
DO NOT perform any moderate exercise during the 24 hours prior to testing
DO NOT perform any extreme exercise, for example running for greater than 10 miles or equivalent, during the 72 hours prior to testing
DO NOT drink alcohol or use drugs during the 24 hours prior to testing

Blood Work: During the MRI we will draw up to, but no more than, approximately 3 tablespoons of your blood may be drawn for a panel of tests. The blood draw will occur at the beginning of the baseline visit. We will place a peripheral venous catheter (IV) to draw blood at the CRC and Vanderbilt University Institute for Imaging Science. We will perform a complete metabolic panel and hemoglobin A1c and will store a small amount of additional blood, which may be used for future studies related to cardiometabolic health.

Fat aspiration: You will undergo a subcutaneous adipose tissue (fat) aspiration on the abdomen before and after the MRI scan. You will lie down, and a 2.5 inch area will be sterilized using a chlorhexidine swab. A drape will be placed over the sterilized area. Lidocaine will be used to numb the skin. A small liposuction catheter will be placed under the skin to collect the fat sample. Approximately 10 ml of tissue will be collected. The procedure takes less than 15 minutes, blood loss is negligible, and generally

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results in no visible skin marks. The bandages that will be applied after the procedure will be removed after 24 hours, and steri-strips will be left in place until they fall off.

MRI Scan: After the first fat aspiration, we will go to the VUIIS for the MRI scans. After you store your valuables in a secure place, you will go into the MRI room and lie down on the table. Straps and pillows will be placed around you so that you don't move during the scan and to increase your comfort. The MRI scan will be no longer than 120 minutes. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, the scans use a strong magnet and radio waves, like those used in an AM/FM radio, to make pictures of your body.

You may not be able to have this scan if you have devices in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, or cochlear implants. Also, you may not be able to have this scan if you have any metal-based tattoos, pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear "hammering", clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them. During the scan, the MRI staff is able to hear and talk to you. They may talk to you during your scan and may ask you to hold your breath, not move, or perform other simple tasks. You may be asked to lie very still throughout the scan. In this study, the MRI scan is for research only. However, if we see something that is not normal, you will be notified and asked to consult your doctor.

Cold Exposure: After taking MRI pictures at room temperature, we will begin the cold exposure protocol. You will be wearing lightweight clothing (running or gym shorts and a t-shirt) for this test session condition. You will lay on a table between two or three water circulating blankets. Throughout the session, the temperature of the water in these blankets may increase or decrease in a controlled manner. You will be asked to indicate your perception of the temperature. Your temperature will be kept high enough to avoid shivering. We will draw blood from your IV up to 6 times during the cold exposure protocol. This protocol will take approximately 1 hour.

DEXA Scan (Body Composition): After your MRI, we will measure your body composition (amount of fat, muscles, internal organs, and bones) using dual-energy absorptiometry x-ray technology(DEXA). Prior to

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your Dexa procedure you will take a urine pregnancy test. If the result is positive, the Dexa will not be done. During this test, you will lie flat on a padded table and the DXA machine will take x-ray pictures of your body, which will be used to calculate how much fat, lean tissue (muscles plus organs) and bones are present in your body. This test will last about 15 minutes.

After the Dexa body composition scan you will be escorted back the CRC where you will undergo your second fat aspiration. This will occur approximately four hours after the beginning of the cold protocol.

Study drug: After your baseline study visit is complete, you will be randomized to study drug or placebo (like a flip of a coin) and a study coordinator will hand-deliver the study medication, which will be either tadalafil or placebo. We will give you 13 weeks' worth of the study medication (tadalafil or placebo). The extra week of pills will allow us flexibility in scheduling your Week 12 visit. We will talk with you about how to take the medication and answer any questions that you may have.

2. Study Procedures that Occur Throughout the Study Period:

Dietary intake: We will assess your dietary intake throughout the study period using an online survey. We will use the Automated Self-Administered 24-hour (ASA24) Dietary Assessment Tool. You will complete the ASA24 on two week days and one weekend day in Weeks 1, 6, and 12. You will receive written instructions for completing this survey and an email or text reminder from the study coordinator to complete the survey during Weeks 1, 6, and 12. It will take approximately 15-20 to complete the survey each time.

Activity monitoring: At the end of the baseline study visit, you will be given a Fitbit device to wear for the duration of the study to measure your physical activity. The study coordinator will assist you with the setup. The device will be synced to your smartphone and all notifications will be turned off. You will return the Fitbit to the study team at your Week 12 visit.

Doubly labeled water process: Doubly labeled water is a radiolabeled (NOT radioactive) form of water that will allow us to measure your body's energy expenditure. We will ask you to drink approximately 8 ounces of radiolabeled water at baseline and again during Week 10. We will collect a urine sample before you drink the doubly labeled water and at least one hour after. You will then collect urine samples at home at specific time points after drinking the water. The time points are described below. You will also be provided an instruction sheet and supplies for collecting urine samples at home. Briefly, men will urinate into a specimen cup and women will urinate into a "hat" that sits on top of the toilet seat. You will use a provided dropper to place 1.5mL of urine into three provided tubes. You will be asked to record the exact date and time of the sample collection using a log that will be provided to you. You will cap the sample vials securely being careful not overfill using pre-labeled sample vials, and you will

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not reuse any of sample collection equipment such as urine cups and transfer droppers after transferring the sample into the sample vials. Zip lock bags will be provided so that you can put the sample vials inside and put the bags into the refrigerator or freezer. We will provide you with pre-paid packaging materials to send the samples back to us and instructions to take home on how to collect and properly package the specimens.

Baseline

- Collect pre-dose urine sample
- Drink first dose of doubly labeled water: Time 0
- Urine sample #1: at least 1 hour post-dose (approximately)
- Urine sample #2: 24 hours post-dose (approximately)
- Urine sample #3: 10 days post-dose
- Urine sample #4: 12 days post-dose

Week 10

- Collect pre-dose urine sample
- Drink first dose of doubly labeled water: Time 0
- Urine sample #1: at least 1 hour post-dose (approximately)
- Urine sample #2: 24 hours post-dose (approximately)
- Urine sample #3: 10 days post-dose
- Urine sample #4: 12 days post-dose (at your 12 week visit)

You will bring 2 samples (urine samples #2 and #3 above) after the Week 10 dose to your Week 12 visit.

3. Week 10 Visit

This visit will take at least an hour and will occur at the Clinical Research Center or Preston Research Building. This visit will involve collecting a urine sample and drinking the second dose of doubly labeled water. We will then collect a urine sample at least one hour after you drink the water. You will then be asked to collect two post-dose urine samples at home, as described above. Your final urine sample will be collected at your 12 week visit.

Follow up:

We will contact you by phone to conduct phone interviews every 2 weeks to assess medication adherence and any symptoms or side effects. You will bring any remaining study medication with you to your last study visit.

Good effects that might result from this study:

You are unlikely to experience any clinically-important benefits over the course of the study. The potential benefits to science and mankind that may result from this study include the knowledge that we will obtain regarding the effect of the study drug on adipose metabolism, gene expression, and body

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composition. The study may lead to more successful treatment of obesity related heart and metabolism abnormalities.

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

Tadalafil: The most common adverse reactions experienced by individuals taking tadalafil 20mg daily are listed below:

Common side effects (>10%)
o Headache
o Dyspepsia (indigestion, bloating, heartburn, nausea, vomiting, burping)
o Back pain

Headaches are the most common side effect. During the first few days of taking the study medication, you may experience a headache as you adjust to taking the medication. If your headache persists, please contact the study team to discuss the duration and severity of your symptoms. The study team will determine whether or not a temporary adjustment to your dosage is necessary, Please do not adjust your dosage without talking to the study team first.

Uncommon side effects (<10%)
o Myalgia (muscle pain)
o Nasal congestion (stuffy nose)
o Flushing (warmth or burning if the face, neck, upper trunk, or abdomen)
o Pain in your arm or leg
o Gastroesophageal reflux disease (heart burn)
o Dizziness
o Nasopharyngitis (nasal obstruction, runny nose, coughing, sore throat, sneezing)

Rare side effects (<1%)
o Myocardial infarction (heart attack)
o Unstable angina (unexpected chest pain while resting)
o Heart failure
o Uncontrolled arrhythmias (irregular heartbeat)
o Stroke
o Sudden visual loss
o Sudden hearing loss
o Priapism (prolonged erection of the penis)

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These conditions are all rare, and whether they are directly related to tadalafil use is unclear. Individuals with a history of these conditions are excluded from participating in this study. If you experience any of these rare symptoms, stop taking stop taking tadalafil and seek medical attention immediately.

Blood collection: Pain, redness, soreness, bruising, or very rarely, infection may occur at the needle stick site. Rarely, some people faint.

Magnetic Resonance Imaging: There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs. You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have this scan if you have any iron-based tattoos, pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye). The Vanderbilt Institute of Imaging Science uses a comprehensive screening form to ensure your safety prior to exposure to the magnet. No contrast will be administered in the proposed protocol.

Cooling Protocol: You will be covered in cold-water blankets which may cause shivering and discomfort. In our studies to date of over 40 individuals, only one study has been terminated due to discomfort related to the cooling protocol.

Subcutaneous Fat Aspiration: Possible risks of the aspiration procedure include pain, local skin irritation, bleeding, bruising, and hematoma at the site. There is potential risk for local or systemic infection, more severe bleeding, or a small scar; however, the risk of these events is extremely low (less than 1 in 500).

Dual Energy X-ray Absorptiometry: This research study involves exposure to radiation from up to 2 DEXA whole body scans. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study is equal to receiving 17 days of radiation from your natural surroundings or less than 1% of the amount allowed in a year for people who are exposed to radiation as part of their work.

Doubly labeled water: Although there are no known risks to ingesting doubly labeled water, it is acknowledged that any research may have unforeseeable risks. The isotopes (2H, 18O) used in the study

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are naturally occurring stable isotopes and are found in our bodies and in the fluids and food we consume every day. These stable isotopes do not emit any harmful x-rays and have been used in studies with premature infants, newborns, children, adolescents, and pregnant and lactating women with no known adverse effects.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Payments for your time spent taking part in this study or expenses:
You will be compensated $500 for completing all aspects of this study. We may ask you for your Social Security number and address before you are compensated for taking part in this study.

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 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 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 the study coordinator at [redacted] If you cannot reach the research staff, please page the study doctor at [redacted].

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:

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We plan to monitor closely for adverse effects and may remove you from the study for symptoms deemed related to the study drug. The inability to tolerate tadalafil or hypersensitivity to the drug will result in withdrawal.

The study doctor may withdraw you from the study if the doctor thinks taking part is not in your best interests. If you cannot give required information, you cannot continue in the study. If you cannot come to appointments, you may be removed from the study. If you are removed from the study, you will be told why.

If you need over-the-counter or new prescription medication during the study, please tell your study contact. You may be removed from the study because some medications interfere with the study.

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.

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:
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.

Consent forms, medical history data, and study data are stored in secured files, either in locked file cabinets or in a locked room separate from medical records and coded such that all subject identifiers have been removed. As an additional precaution all HIPAA regulated information is stored in an electronic file separate from other study data. Only approved study staff (determined by Drs. Brittain

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and Damon) will be given authorization to access the database. Bio-specimens are processed and labeled with barcode labels that include the subjects electronically generated study code and date of sample collection. The bio-specimens are stored in locked freezers in the study Laboratory; only approved study staff has access to the keys for each freezer. Access to the electronic freezer inventory of the specimens is kept on a secure password protected computer.

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.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. The National Institutes of Health, Vanderbilt, Dr. Brittain and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Study Results:
Results from this study will be available to the public upon conclusion of the study and subsequent data analysis on clinicaltrials.gov.

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?
All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study,

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you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below. As part of the study, Dr. Brittain and his study team may share the results of your study blood work as well as parts of your medical record, to the groups named below. People from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board, who might review this study to ensure we are following all local and Federal guidelines for patient protection. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

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?
The study results will be kept in your research record for at least six years after the study is finished.

At that time, the research data that has not been put in your medical record will be destroyed. Any research data that has been put into your medical record will be kept for an unknown length of time. Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Brittain in writing and let him know that you withdraw your consent. His mailing address is [redacted]. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

By signing this authorization, you consent to being contacted in the future regarding other 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.

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.

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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: _____

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