PRINCIPAL INVESTIGATOR: Josephine M. Earley, M.D

STUDY TITLE: Sodium-glucose Co Transporter 2 (sGLT2) Inhibitor and Endogenous Ketone Production

STUDY SITE: National Institute on Aging at MedStar Harbor Hospital

Cohort: Healthy volunteers age 55 and older

Consent Version: 05/05/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

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This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This study is being done to look at how your body responds to a medication approved by the Food and Drug Administration (FDA) for treating diabetes. The medicine is called empagliflozin (Jardiance). Diabetes is a disease that occurs when your blood glucose, also called blood sugar, is too high. Empagliflozin (Jardiance) lowers blood sugar by increasing the amount of glucose excreted by the kidneys. This results in more than usual amounts of ketones being formed in the blood stream. Ketones are made when your body either does not have enough glucose available or cannot use glucose as fuel for its energy needs. They are made in the liver mostly from the breakdown of fats. We would like to study whether giving empagliflozin (Jardiance) to you and other people who do not have diabetes will increase the amounts of ketones in your blood. This medication does not lower blood glucose levels below usual levels in people without diabetes.

Normally, the food in our diets is broken down into glucose (sugar), fats and amino acids. These are then used as fuel sources for energy. Food products that are not needed right away as fuel by the body are stored in the liver, fat and muscle tissue for future use. During fasting periods and overnight, the body will adapt by using the fuel that is stored, mainly as fat. The breakdown of the stored fat results in ketones being released into the blood stream. These ketones are taken up by the brain and other organs and are used as energy in place of glucose. When the brain burns ketones for energy instead of glucose it changes brain metabolism. Many people with age-related neurological diseases, such as Alzheimer's Disease, share the problem that their brain cells do not use glucose as well as they used to when they were younger. Research has shown that when fuel is supplied to the brain in the form of ketones, memory and mental tasks seem to improve in older animals. We would like to study what will happen to your ketone levels while taking the study drug for about 2 weeks. We believe it will cause an increase in ketones in your blood and other people without diabetes. In the future, we would like to see if we could use this medication to improve brain health in people as they age.

What if I am presently participating in another study?

Are you presently participating in any other research studies? Yes ☐ No ☐

If yes, please state which study (ies) _____

If you are taking part in another study, the investigator wants to make sure that it is safe to be in this study. This will protect you from things such as extra blood drawing or drug interactions.

Screening Visit (Visit 0)

We will ask that you do not eat anything for 8 hours before the screening visit. You may drink water. We will take a health history and perform a physical exam. You will have a blood draw. About 2 tablespoons of blood will be drawn at this visit. The screening visit will last about 1.5 hours. Following the visit, a snack or meal will be provided.

Screening Visit Procedures

Medical history and physical examination:
One of the doctors or nurse practitioners will review your medical history. You will change into a hospital gown. We will measure your height, weight, body temperature, and blood pressure, breathing and pulse rates. This will take about 30 minutes.

Fasting Blood Samples:
Blood will be drawn for a complete blood count (CBC), liver and kidney function, thyroid function, glucose and basic chemistry (CMP). You will also be tested for Human immunodeficiency virus (HIV), Hepatitis B, and Hepatitis C viruses.

Hepatitis B and Hepatitis C Testing:
This study requires that your blood be tested for these diseases that can be spread through your blood. You will be informed of the results of these tests. If you have Hepatitis B or untreated Hepatitis C, you will not be eligible for the study and the results will be reported to the state health department. If you are infected with any of these viruses, we will tell you what the results mean, how to find care, how to avoid infecting others and informing your partners of possible risks.

Human immunodeficiency virus (HIV) test:
As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will not be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infection, and the importance of informing your partners at possible risk because of your HIV infection. If you decide not to provide an HIV blood sample, you will not be eligible to participate in the study.

Urine Sample:
A urinalysis will be done to check for glucose (sugar) in your urine. If you have glucose in your urine at the screening visit, you will not be eligible to participate in this study.
If you are eligible after the screening visit, there will be 3 study visits. These visits will be scheduled about 13 days apart. All these visits will involve the same study procedures. The only difference will be on Visit 1, you will not receive any study medication. We want to see how your glucose, insulin and other hormones respond before and after taking the study medication.

Study Visit (Visit 1)

You will arrive on the NIA Clinical Research Unit for a 2-day visit. We will ask that you do not eat or drink anything except water for 8 hours before your visit. We will place an intravenous (I.V.) catheter into an arm vein. We will use this catheter to obtain frequent blood samples every 1-2 hours for 34 hours. You will have a continuous glucose monitor (CGM) placed to measure your blood sugar during your visit. This monitor is commonly use in people with diabetes and will be worn until you return for Visit 2. During your visits, your meals will be provided, and we will ask you to drink plenty of water. We will ask you to record the time and items you eat during your study visits on a Food Diary. On the evening of your arrival day, you will be given an activity monitor and asked to walk approximately 2,000 steps on the unit after your evening meal, but before bedtime. That evening you will be asked to fast after 7:00 p.m. About 165 ml (11.2 tablespoons) of blood will be drawn at this visit.

Visit 1 Procedures

Fasting Blood Samples / Frequent blood draws:

Blood will be drawn for liver and kidney function, glucose, basic chemistry (CMP), proteins, lipids, ketones, insulin and other hormones. We will also look at various chemicals that are possibly related to age-related cognitive decline and metabolism for research purposes only. Since the significance of these research tests may not be known, we will not share these results with you or your primary care provider.

Urine Sample and 32-hour Continuous Urine Collection:

A urinalysis will be done to check for glucose (sugar) in your urine. We will also collect your urine throughout the visit to measure hormones and to determine how well your kidneys function.

Continuous Glucose Monitoring System (CGM):

This monitor consists of a small sensor that is placed by using a small needle just beneath the skin on the back of your upper arm. It will measure glucose levels in daily living and is used frequently in patients with diabetes to evaluate their treatments and guide their care. In this study, it will be used to record your blood glucose levels both during your stay and while you are at home. You will not be able to see your blood glucose values in real

time. The device will be downloaded and reviewed by the investigators after the sensor is removed. The monitor will be inserted by the staff and you will be trained on using the device and who to call with questions or problems.

Food Diary:

You will be asked to write on paper, the time and what items you eat and drink during your 2-day visits. We will aim to have you eat similar items during visits 1-3.

Intake Diary Instructions:

You will be asked to write on paper, the time you eat and drink anything besides water while you are wearing the Continuous Glucose Monitor.

Symptom Review Questionnaire:

On each visit you will be asked questions to see how you are feeling. These questions will let us know if you are having any side effects from the study.

Activity Monitor:

On the evening of Day 1, on all of your visits a staff member will assist you to wear a device on your wrist that records the number of steps you walk. We will ask that you do your best to walk at least 2,000 steps following dinner and before bedtime. Following Visit 2, while you are taking the study medication at home, we will instruct you to wear the monitor continuously for about 13 days and ask that you walk approximately 2,000 steps every evening, following dinner and before bedtime.

Magnetic Resonance Spectroscopy/ Magnetic Resonance Imaging (MRS/MRI scan):

MRI/MRS uses a strong magnetic field and radio waves to take pictures of your brain, measure its blood flow and function. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will lie on a table that can slide in and out of the cylinder. A plastic device called a "coil" will be placed over your head. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at any time. The entire procedure should take about 60 minutes. You will complete a screening form before you are allowed to perform the MRI and if it is determined that you meet any criteria that would exclude you from the MRI (for example pacemakers and some metal implants) then you will not be able to participate in this study.

Study Visit (Visit 2)

This visit will take place approximately 13 +/- 2 days following Visit 1. It will be the same as Visit 1, except you will be given the study drug empagliflozin (Jardiance) 25 mg followed by breakfast on both mornings of your visit. You will be asked to continue taking the study drug at home once a day, in the morning followed by breakfast within 30 minutes. You will take the study drug at home for about 13 days. You will wear the Continuous Glucose Monitor (CGM) until you return for Visit 3.

A staff member will contact you daily to make sure you have taken the study medication and monitor you for any symptoms.

If you should have any symptoms while you are taking the study medication at home, call Dr. Earley at 410-294-4759 or Dr. Chia at 410-900-2216.

We will draw the same blood work as Visit 1. In addition, we will check your blood count to determine it is safe for you to again have the frequent blood sampling. About 168 ml (11.4 tablespoons) of blood will be drawn at this visit. If your blood count is found to have decreased more than 10% from the screening visit, we will then reduce the number of blood draws to every 2 hours for the remainder of the visit. In this case the amount of blood taken will be about 130 ml (8.8 tablespoons). In addition, we will conduct the same MRS/MRI scan lasting about 1 hour.

Study Medication

Empagliflozin (Jardiance) is a pill used to treat type 2 diabetes. It works by helping the kidneys remove glucose from the bloodstream through the urine. The usual dose is 10 mg or 25 mg. The dose we will be studying is 25 mg.

Study Visit (Visit 3)

This visit will take place approximately 13 +/- 2 days following Visit 2. It will be the same as Visit 2 (including the same MRS/MRI scan). When you complete this visit, you will no longer take the study medication or wear the Continuous Glucose Monitor (CGM). A staff member will contact you within one week to see if you have any symptoms.

Risks, Inconveniences and Discomforts

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator(s) and/or your regular doctor. We encourage you to speak with your family and friends about any risks involved before deciding to make a decision. Potential risks and side effects related to this study are described below.

Risks and side effects that may occur include:

Risk of Study Medication - Empagliflozin (Jardiance):

While on the study medication you are at risk for the side effects as described below. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. As with all medications, undesirable events are sometimes experienced. This includes a hypersensitivity (allergic) reaction. Side effects reported with empagliflozin were dehydration, dizziness, lightheadedness, weakness, yeast and urinary tract infections.

Empagliflozin will result in you excreting more sugar than usual in your urine. More water will also be pulled into your kidneys. This may cause you to urinate more than is usual for you. Because of the added sugar in the urine, bacteria and yeast are more likely to grow in your pelvic area and bladder. To decrease these risks, we will encourage you to drink lots of non-sugary, non-energy containing fluids. We prefer that you drink water or flavored water and maintain good hygiene. We will ask that you drink 8 ounces of water every 4 hours, except when you are asleep.

_____ Placing my initials here, means that I understand the importance and agree to drinking 8 ounces of water every 4 hours, except when I am asleep during the times I will be taking the study medication.

Other side effects may include nausea, which can occur with any drug taken by mouth, and upper respiratory tract infections. Rarely, sudden episodes of kidney failure or kidney damage may occur. The FDA has issued a warning about a serious infection of the genital area (necrotizing fasciitis of the perineum) associated with this class of drugs. This infection has rarely occurred, and non-diabetics have generally not taken this medication. In order to prevent many of these side effects, we encourage you to drink water and to maintain good hygiene (bathe or shower daily). We will contact you daily to assess for any symptoms, i.e. tenderness, redness or swelling of the genital area, fever or general feeling of being unwell.

Risk of Medical history and physical examination:

There are no risks to having a physical exam.

Risk of blood drawing/ I.V. placement:

It may hurt a little when we stick you with the needle. You may get a little bruise (black-and-blue mark). Some people feel dizzy or faint when they have blood drawn. To reduce the risk of injury because of a fall, you will be closely monitored and asked about these symptoms before you can stand. There is minimal risk that you may get an infection by puncturing the skin. During the frequent blood sampling, the I.V. catheter may stop working and the I.V. may need to be reinserted to obtain the blood samples. The amount of blood drawn is within the NIH guidelines which are 550 ml (2.3 cups) in an 8-week period. The total amount of blood collected if you are eligible for this study is no more than 531 ml (36 tablespoons or about 2 ¼ cups).

Risk of Hepatitis B, Hepatitis C and HIV testing:

The results of these blood tests, if positive, will be reported to you and the state health department.

Risk of Incidental Findings:

It is possible that one or more of the tests undertaken as part of this study will show that you have a condition you did not know about or that will need to be investigated. It is possible that discovering a condition may make obtaining insurance difficult in the future.

Risk of Continuous Glucose Monitor:

Potential risks include a slight skin irritation from the adhesive.

Risk of Magnetic Resonance Spectroscopy/ Magnetic Resonance Imaging (MRS/MRI scan):

People are at risk for injury from the MRI magnet if they have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You will be screened for these conditions before having any scan, and if you have any, you will not receive an MRI scan. If you have a question about any metal objects being present in your body, you should inform the staff. In addition, all

magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away. Please notify the investigator if you have hearing or ear problems. You will be asked to complete an MRI screening form for each MRI scan you have. There are no known long-term risks of MRI scans.

Incidental findings (brain MRI scan):

A potential risk of participating in this study is that the radiologist who reviews brain images may find a brain abnormality of uncertain significance. We will inform you about any finding that may require further evaluation or care. We are not able to provide evaluation or treatment for these conditions at NIH. If needed, we will refer you to a health care provider. We may not inform you about minor abnormalities that do not have importance for your health or wellbeing.

Risks associated with Stored Specimens:

What will happen to the samples and information that are collected during the study?

Samples of your blood and tissue may be kept in a research laboratory at the National Institutes of Health or one of our contract facilities. Your samples may be tested immediately, or they may be frozen and used later. The greatest risk associated with stored samples is the unplanned release of information from the medical records. The chance that this information will be given to an unauthorized person without your permission is very small. Possible problems with the unplanned release of information include discrimination when applying for insurance or employment. Similar problems may occur if you disclose information yourself or agree to have your medical record released.

Samples may be kept indefinitely or until no cells and/or tissues remain or until the investigators decide to destroy them. Your name and identifying information will be removed and we will assign the sample a code. The key to the code will be kept in a separate, secure area. Research records with personal identifiers (such as your name) will be stored in our locked offices, the medical record department, and the electronic study data base. Any identifying information about you will be kept confidential to the extent permitted by law. The NIA will retain custody of your samples for studies as outlined above.

The NIA will be exclusive owner of any data, discoveries or derivative materials from the sample materials and is responsible for the restriction of sample use at your request. If a potential commercial product is developed from the research project, the NIA will develop patents and promote commercialization of the product as required by law. You will not profit financially from such a product.

Are there any benefits to you if you take part in this research study?

This study is not designed to provide direct benefits to any participants. We hope the information learned from this study will benefit others in the future.

What choices you have besides taking part in this study?

You have the choice not to participate in this study.

Results From this Study

We will provide you with a copy of your screening clinical laboratory blood work within 1-3 weeks of your screening visit. You will also receive any other clinically significant lab results from your remaining study visits. We will also provide you copies of your MRI reports should the results show that you need further evaluation or care.

What if I want to withdraw from the study?

You may voluntarily withdraw from this study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled.

Any data or blood collected will remain part of the study and the property of the National Institute on Aging. You may request that we destroy any remaining blood/tissue by contacting the Principal Investigator (see page 6 for contact information). If you suddenly decide to stop participating in the study, we do not know of any serious consequences. However, we do encourage you to talk to the investigator. There are conditions that may require us to withdraw you from the study, including but not limited to the following:

- You are unable or unwilling to comply with the study requirements.
- The Principal Investigator, Dr. Josephine M. Earley, deems it unsafe for you to remain in the study.
- The study is terminated.

Discussion of new findings

If any new information is learned, at any time during the research, which might affect your willingness to participate in the study, we will tell you.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

This study will provide compensation in the form of a debit card upon completion of your visit.

You will receive $30 for completing the screening visit. You will receive $540 for completing Study Visit 1; $600 for completing Visit 2 and $700 for completing Visit 3. The total compensation for successful completion of this study will be $1870. Should the study physician ask you to return for any unplanned visits, you will be compensated $20.

If you are unable to finish the study, you will receive compensation for the parts you completed as follows:

Frequent blood sampling	140 dollars
Continuous Glucose Monitor	150 dollars
Food Diary (in-patient)	20 dollars ($10/day)
Intake Diary (out-patient)	65 dollars
MRI	125 dollars
Activity Monitor/completing steps	25 dollars

34-hour urine collection	50 dollars
Study medication (self-dosing)	100 dollars

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines. This study does not offer reimbursement for, or payment of, travel or lodging. Meals will be provided in the form of a food voucher.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH. You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company.

Conflict of Interest

The investigators and personnel involved in this study do not have any conflicts of interest to disclose. The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf. You may ask your research team for additional information or a copy of the Protocol Review Guide.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Research records will be kept using secure computers. These are password protected and maintained on a secure server with access limited to authorized NIA staff members. All NIH investigators and NIA staff members who have access to these databases have the proper training on patient privacy as well as the required Human Subject Protection Training.

Your samples will be stored in a secured area at an NIA facility. The only information on the sample is your study ID number. The key to the ID number will be kept in a separate, secure area to which only the clinical study staff have access.

We will ask you for your social security number in order to compensate you for your participation. If you do not wish to provide this information, you may still participate. However, you may not be able to receive compensation.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

NIA will provide short-term medical care for any physical injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, NIA, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Josephine M. Earley, M.D. eganj@mail.nih.gov; 410-350-3922; Other researchers you may call are: Chee Chia, M.D. at 410-350-7376; Ajoy Karikkineth at 410-350-3970; You may also call the Clinical Director at (410) 350-3922; the NIA Clinical Research Protocol Office at (410) 350-3947, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

IRB NUMBER: 19AG0060
IRB APPROVAL DATE: 05/13/2020