Determinants of Alpha-aminoadipic Acid (2-AAA) and Relationship to Diabetes: Study 3

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VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Determinants of alpha-aminoadipic acid (2-AAA) and Relationship to Diabetes: Study 3 Lysine Tracer
Version Date:	1/5/2022
PI:	Jane F. Ferguson, PhD

Name of participant:_____ Age:_____

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

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:

1. **What is the purpose of this study?**

We are studying a metabolite called α-aminoadipic acid (2-AAA). 2-AAA occurs naturally in the body. Different amounts of 2-AAA may alter the risk of developing diabetes. We are interested in whether acute lysine administration results in variability of increased plasma 2-AAA levels.

2. **What will happen and how long will you be in the study?**

You were selected as a candidate based on your participation in a previous phase of the study. We will ask you questions via email or over the phone to determine eligibility.

If eligible, you will complete a single study visit. It will take you approximately 7 hours to complete the study. The single study visit will be conducted at the Clinical Research Center (CRC) at Vanderbilt University Medical Center.

We will give you a drink containing lysine and take samples to measure the level of 2-AAA in your blood and urine before and after your lysine administration. You will be asked to provide a urine sample for baseline 2-AAA measurement and will undergo a urine pregnancy test (if you are of child-bearing potential). A light snack will be provided to you following the study visit.

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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 were selected as a candidate based on your participation in a previous phase of the study.

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 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.

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

Venous Blood Draw: This is a routine procedure that is considered standard of care in clinical medicine. All blood draws will be performed by trained personnel using universal precautions to protect both the study participant and personnel. The risks to study participants are minimal, but you may experience pain, an allergic reaction, bleeding or bruising where the intravenous (IV) needle is placed. Occasionally, a person feels faint or lightheaded when their blood is drawn. These usually resolve without any specific therapy over the course of minutes to days. Rarely an infection can develop; it can be treated.

Lysine Ingestion: Lysine is used as a dietary supplement, available over the counter, with no known long-term risks. Lysine is expected to be well-tolerated by all study participants. There are no additional risks associated with the use of stable isotope tracer ^{13}C lysine. The proposed dose of lysine may cause mild gastrointestinal upset in some study participants. This is expected to be minor and transient.

Private Health Information: This information will be collected during the study. However, only key study personnel will have access to this information, which will be stored in a HIPAA compliant, password protected database. No protected health information will be shared with employers, insurers, or non-research personnel.

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4. Good effects that might result from this study:

You will not benefit from taking part in this study. The results of this research study may advance our understanding of a biomarker for Diabetes and help to guide the development of novel preventative and therapeutic strategies. This could benefit patients in the future.

5. Procedures to be followed:

Screening will be conducted by email, and/or via phone. We will email or call you about the study, review the inclusion/exclusion criteria, and send you the link for e-Consent. If you do not qualify for any reason, the study staff will tell you why.

Study Visit:

Upon arrival, the consent form will be reviewed to confirm that you still wish to participate. You will be asked to arrive fasting (≥ 8 hours). This means that you cannot eat or drink anything (with the exception of water) for at least 8 hours before your visit. We will review your medical history, medications, and inclusion/exclusion criteria, which will be documented by study personnel to assess for any changes that may potentially exclude you from participating. We will measure your blood pressure, height, and weight prior to study interventions. You will be asked to provide a urine sample for baseline 2-AAA measurement and will undergo a urine pregnancy test (if you are of child-bearing potential).

Following the baseline urine sample, we will place a small tube in the vein of your arm to take blood. A baseline blood draw will be taken for measurement of baseline plasma 2-AAA levels and related biomarkers. Next, you will be given a drink containing L-Lysine in 50mL of water. This amount is equivalent to the lysine content in a 5 oz. serving of beef. Blood samples will be taken at time= 30 mins, 1, 2, 3-, 4-, 5- and 6-hours post-lysine administration. Normal Saline (0.9%) will be infused in the vein of your arm to flush the canula prior to each blood draw, and a 3-5mL blood discard will be performed prior to each collection of samples. Each blood draw collection (including baseline) will collect about 20cc of blood, for a total collection of 160cc, or approximately 11 tablespoons of blood. Urine samples will be collected throughout the visit, in 2-hour increments (0-2, 2-4 hrs. and 4-6 hrs. post-lysine). You will be asked to remain seated for the duration of the study but will be permitted to walk for bri ef periods throughout the study (e.g., to use the restroom).

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

Individuals that complete all the required study activities will be compensated with $150. This will come in the form of a check that will be mailed to your home; it typically takes about 4 weeks to arrive. We

will need to collect your full social security number and address before you are compensated for taking part in this study, and any income you make from participating in clinical research could be taxable if you make $6700 or more in one year. You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the US. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

7. Costs to you if you take part in this study:

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

8. Payments in case you are injured because of this research study:

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

There are no plans for Vanderbilt or the National Institutes of Health (NIH) 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 or the National Institutes of Health to give you money for the injury.

9. 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 [redacted] or the Clinical Research Coordinator [redacted] or [redacted]. If you cannot reach the research staff, please contact [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.

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

The study investigator may remove you from the study if you experience complications during any of the discussed procedures. You will also be removed if you are not compliant with treatment or procedures.

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11. 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 the Principal Investigator. Deciding to not be part of the study will not change your regular medical care in any way. 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 her know. Her mailing address is:

[redacted]

Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you canceled your authorization. You will get a copy of this form after it is signed.

12. 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.

13. Confidentiality:

Your study records and data will be stored in a secure database. The database will reside in a password protected secure website supported by Vanderbilt University. Only study personnel will have access to the database.

Information in the database that will identify you will only be available to study personnel.
Your biological samples will be stored with a study ID label. This label will not include any identifying information. Only key study staff will have access to your identifying information.

All key study personnel at Vanderbilt University involved in the design or conduct of this study will receive the required education on the protection of human participants. This study will follow the relevant federal guidelines regarding HIPAA regulations on patient-related information. Only key study personnel will have access to identified information.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Ferguson, or her 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.

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 legalmeans.

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.

14. 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.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

15. Study Results:

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you will be notified so you can make a decision whether or not to continue your participation in thisstudy.

Your study records and data will be stored in a secure database. The database will reside in a password protected secure website. Information in the database will only be available to study personnel. Your biological samples will be stored with a study ID label in a locked freezer. This label will not include any identifyinginformation. Onlykey study staff will have access to your identifying information. All key study

personnel involved in the design or conduct of this study will receive the required education on the protection of human participants.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

16. Authorization to Use/Disclose Protected Health Information

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

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

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

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

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What if you change your mind?
If you decide to stop being part of the study, you should tell the Principal Investigator. Deciding to not be part of the study will not change your regular medical care in any way. 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 her know. Her mailing address is:

[redacted]

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. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

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

In-Person Consent:

I confirm that I freely and voluntarily choose to take part in this study.

Date Name of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title Time

Date of IRB Approval: 02/07/2022
Date of Expiration: 02/01/2023

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Consent for Sample and Data Storage and Future Research:
You are being asked to give blood and urine samples for research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

Multiple blood samples totaling 11 tablespoons will be drawn from a vein in your arm using a needle; urine will be obtained by self-collection throughout the study visit; The entire study visit will take about 7 hours of your time.

Blood samples – The risks to study participants are minimal, but you may experience pain, an allergic reaction, bleeding or bruising where the intravenous (IV) needle is placed. Occasionally, a person feels faint or lightheaded when their blood is drawn. These usually resolve without any specific therapy over the course of minutes to days. Rarely an infection can develop; it can be treated. You may feel bothered or pained from the needle stick.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only the PI, Jane F. Ferguson, and trained study personnel (including Stacy Desine, Holly M. Smith) will have access to your name.

Your sample will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

At any time, you may ask to have your sample destroyed. You should contact [redacted] to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for research.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future research in diabetes.

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☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future research for other health problems (such as cancer, heart disease, etc.).

☐ Yes ☐ No

Signature:_____Date: _____