Acute effects of dietary oatmeal on serum levels of N-acyl-phosphatidylethanoleamines and their metabolites.

NCT03468179

July 2, 2018

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Sean S. Davies Ph.D. Version Date: 05/01/18
Study Title: Effects of Oatmeal Challenge on N-acyl-phosphatidylethanolamine
Institution/Hospital: Vanderbilt University

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.

You do not have to be in this research study. 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. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

The purpose of this study is to find out if eating oatmeal, a common breakfast food, will increase the blood levels of a lipid that has shown to have protective effects against obesity and inflammation.

Ten (10) people will be enrolled in this study at Vanderbilt.

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

Screening Day
If you agree to be in the study, we will ask you to come to the Vanderbilt Clinical Research Center (CRC) for a screening visit. We will do a physical exam and ask you about your medical history.

If you are eligible for the study, we will schedule a day to come back to the CRC.

Study Day

You will come to the CRC in the morning. It is important that you have nothing to eat or drink after 10pm before you come.

We will insert a small tube in the vein in one of your arms. We will take a blood sample (about 5ml or 1 teaspoon) from the tube. We will then give a bowl of oatmeal to eat. We will take blood samples (about 1 teaspoon each) at 30, 60, 90 and 120 minutes after you eat the oatmeal.

You will then be done with the study day.

Your 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 or other identifying information. You will not receive any benefit as a result of the tests done on your samples.

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, and/or others. If this happens, there are no plans to provide money to you.

May we contact you in the future regarding other studies for which you are eligible?

☐ Yes ☐ No

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

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

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

Inconveniences

- Not eating or drinking after midnight on the night before the study
- Eating a special diet (bowl of oatmeal).
- Traveling to the CRC.

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Risks of the Catheters

Putting a catheter into your vein to draw blood may cause pain, redness, soreness, bruising, or infection at the needle stick site. Rarely some people faint. We will use careful and sterile techniques to minimize these side effects.

5. Risks that are not known:

There may be risks that we do not know about at this time.

6. 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 the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study – we may learn more about how eating oatmeal provides long-term health benefits.
b) The benefits you might get from being in this study. None.

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You can choose not to be in the study and nothing about your healthcare will change.

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

If you complete the study, you will be paid $60 for your time.

We may ask you for your Social Security number and address before you are compensated for taking part in this study.

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

You may be removed from this study without your consent if:

- Staying in the study would be harmful to you
- You no longer meet the requirements of the study
- The study is stopped.

If you are removed from the study, you will be told the reason.

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 your study doctor.

12. 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 Dr. Jordan Wright, of the research team, at 615-343-8332**.**

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 Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. The study results will be kept in your research record for at least seven years after the study is over for as long as we need the information for the study. All the information on paper will be kept locked in a secure location. Any information kept in a computer will be through the Vanderbilt CRC data system, which has many safeguards. Only members of Dr. Luther's research team will be able to see any of the information that would identify you. Any research data entered into your medical record will be kept as long as it is needed.

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

15. Authorization to Use/Disclose Protected Health 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, 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. Davies and his study team may share the results of your study and/or non-study linked lab tests as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and