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Postprandial Inflammation and Nuts (PIN) in Older Adults (PIN)

ClinicalTrials.gov ID NCT06348771
Sponsor Rutgers, The State University of New Jersey
Information provided by Sue A. Shapses, Ph.D; Rutgers, The State University of New Jersey (Responsible Party)
ID: Pro2023001579

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Postprandial inflammation and nuts in older adults
Principal Investigator: Sue A Shapses, PhD

STUDY SUMMARY: Lipopolysaccharide (LPS, also known as endotoxin) is a toxin that can cause an inflammatory response after food consumption. Also, it is now known that certain foods, especially those that are high in fat or highly processed affect serum endotoxin levels. In addition, patients with low grade inflammation, such as in those with excess adiposity generally have higher inflammation compared to lean persons and increased intestinal permeability allowing for a greater rise in serum endotoxin after meal consumption. Furthermore, it is known that fat intake and the type of fatty acid (saturated or unsaturated) will have a differential effect on the rise in endotoxin and inflammation after a meal in young healthy men. In this study our primary goal is to determine the postprandial effects of a meal higher in monounsaturated fatty acids (using peanuts) compared to a meal high in saturated fatty acids on inflammation and satiety in older adults who are overweight or obese.

The **purpose of the research** is to examine whether postprandial metabolic endotoxemia (measured by LPS) affects inflammation after a moderately high fat meal that is enriched in either saturated fatty acids (SFA) or monounsaturated fatty acids (MUFA). Specifically, we will determine whether a meal with peanuts (high MUFA) or one with fat primarily from butter (high in saturated fat) shows a differential effect on postprandial blood endotoxin and markers of inflammation A secondary goal will be to examine bone turnover markers and hormonal regulation of inflammation. If you take part in the research, you will be asked to consume 2 different test meals and participate in 2 days of testing that require you to visit the clinical research facility separated by ~ 1 week. Following a few days of a lower fat intake, you will consume each test meal. Blood will be drawn approximately hourly for 6 hours and you will return the following morning to give a fasting blood and urine sample. Your time in the study will require 7 hours to consume the test meal and to sit comfortably between blood draws (eg., reading or working on a computer) during the intermittent collection of blood samples.

Possible harms or burdens of taking part in the study are no more than minimal and do not exceed those normally encountered in daily activities or routine medical examinations. The only discomfort in this study is the blood drawing which will result in a temporary slight discoloration in the skin surrounding it. Some people experience dizziness and/or fainting when blood is drawn. It is important to inform the research staff if you have a history of fainting. The DXA measurement will produce a small amount of radiation which is equivalent to or less than that received during one day of background radiation. High fat meal consumption may cause some mild gastrointestinal discomfort. The benefits of participating in this study include information about your blood glucose and lipid levels that will be measured during screening. However, you may not receive direct benefit from participation in this study. Your participation in this study may lead to an increased understanding of how diet and other factors contribute to inflammation and postprandial endotoxemia.

In addition, you may withdraw from the study at any time without penalty. Also, if your glucose indicates you have diabetes after the first test day, you will be asked to withdraw from the study so that you can follow up with your physician. If you are unable to complete the study, you will receive a pro-rated monetary compensation based on when you withdraw.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Sue Shapses, PhD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Sue Shapses may be reached by phone at 848-932-9403 and by email at shapses@rutgers.edu. Mailing address at Foran Hall, 59 Dudley Rd, New Brunswick, NJ 08901. The principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
The purpose of the study is to determine whether a moderately high fat meal enriched in MUFA or SFA will differentially raise blood endotoxin or inflammatory levels in older persons with excess adiposity (either overweight or obese).

Who may take part in this study and who may not?
Older (55 years of age or older) men and women from any ethnic group and body mass index (BMI) 25-42 kg/m^2 will be recruited. Subjects will be recruited to the Center for Human Nutrition, Exercise & Metabolism at the Institute of Food, Nutrition and Health (IFNH) in New Brunswick. All participants will sign an informed consent approved by the Institutional Review Board for the protection of human subjects in research prior to participation in these studies. All participants will have to pass a three-step screening process using the telephone (or electronic), laboratory tests, and a physical screening to participate in this study. Participants will fill out a medical and nutrition history, 24-hour recall, and undergo a blood metabolic panel and liver function tests to confirm they meet the inclusion criteria.
Exclusion/Inclusion Criteria - We will only include adults 55 years of age or older (women who report no menstruation for at least 2 years prior to the study). Individuals with diabetes or an elevated panel of liver function tests, with untreated hypertension, current treatment of cancer, inflammatory disease, gastrointestinal disease or who are taking medication or have conditions known to influence inflammation or gastrointestinal absorption (e.g., no pre- or pro-biotics, or evidence of Celiac disease, Crohn's disease) or persons prescribed medications that could affect the GI track (e.g., bisphosphonates or women taking hormone replacement) will be excluded.

Why have I been asked to take part in this study?
You are being invited to take part in the study because you meet the above inclusion and exclusion criteria.

How long will the study take and how many subjects will take part?
This study will take approximately 3 weeks, but you are only required to participate in a screening day (about 1 hour) and 2 additional days (~7 hours each) with approximately a week between these test days. You will be given a comfortable room where we ask that you plan to do seated activities such as reading a book, computer activities or work. You will be required to attend an initial nutrition and medical history screening to determine if you meet the study criteria. You will record food intake for 3 days prior to each test meal and adhere to a lower fat diet during this time. On the test day, a fasting blood sample will be drawn and then you will consume a meal. Following meal consumption, blood samples will be collected hourly for 6 hours after the meal (total of 7 blood draws on this test day~~).~~ On the day of the meal with blood samples collected, the amount of activity needs to be controlled and minimal, so you will be asked to remain in the testing center location during the test-meal study with subsequent blood collection. You will be one of 16 subjects who complete both test days. The full study for all participants will last for a total of 1 year or until we meet recruitment requirements.

What will I be asked to do if I take part in this study?
During initial screening for this study, you will be questioned about your nutrition and medical history to determine if you meet the study criteria. During the initial screening, you will have a blood pressure, weight, height, waist and hip circumference measured. You will have less than 2 Tbsp. of blood drawn to assess fasting blood glucose, lipid levels, and liver function. This will be collected in the morning after an overnight fast before you eat or drink in the morning (water is allowed) in Foran Hall at Rutgers University, New

Brunswick. Blood will be collected by a certified phlebotomist, medical technician or nurse. You will have your body composition measured by a dual-energy x-ray absorptiometry (DXA) machine before the study. The x-ray tests take ~45 minutes and will be in Foran Hall. You may be asked to perform these measurements twice as part of routine quality control for these instruments that will take about another 5 minutes. If these services were obtained outside the study, they would cost more than $180, but will be performed at no cost to you whether or not you continue participation in the study.

The test meal will consist of higher fat foods that either have peanuts or other sources of fat. One meal will have an English muffin, butter and eggs, and the other meal will consist of 1oz whole peanuts, plus 2Tbs natural peanut butter and 1 tsp peanut oil on an English muffin. You will be randomly assigned to a specific sequence of the 2 interventions using statistical software. Test days will be located either in Foran Hall or in the Center for Human Nutrition, Exercise, and Metabolism at Rutgers University, New Brunswick, NJ (locations are at the Institute of Food, Nutrition and Health clinical facilities). We will examine the postprandial response to a peanut or control meal without nuts, given in random order (and 4+ day washout) to avoid a conditional effect. You will be asked to adhere to a lower fat diet (less than 30% fat) 3 days prior to each test day, and to record your dietary intake during this time.

On the evening before each test day, you will eat a meal following guidelines at home and finish eating by 9:00 pm. No food should be consumed afterwards. You will be allowed 2 cups (500 ml) of water (no other fluids) between 9:00 pm and the next morning. You will be required to complete 3 days of food intake when you are enrolled in the study and prior to each test.

On each test day, blood will be drawn for a baseline and fasting measurement of your biomarkers. After the breakfast meal is consumed, less than 2 tsp. of blood will be drawn at 30, 120, 180, 240, 300 and 360 minutes to assess serum endotoxin and inflammatory markers. You will complete this procedure twice. If you are unable to comply with the protocol (e.g., unable to consume breakfast, etc.), then the investigators may ask you to terminate your participation in the study. This is a randomized study, which means that you and the researcher will not know which meal you will be assigned first (the order will be random).

Table 1: Schedule of Events and Sample Collection

Days	Screening	Week 1	Week 3
Informed Consent	X		
Inclusion/Exclusion Criteria	X		
Medical History	X		
Nutrition History	X		
Food recall	3 days	3 days	3 days
Height, weight	X		
Blood draw	X	X	X
Appetite visual scale		X	X
Body composition and bone	X		

What are the risks of harm or discomforts I might experience if I take part in this study?
Possible harms or burdens of taking part in the study are no more than minimal and do not exceed those normally encountered in daily activities or routine medical examinations. The only discomfort in this study is the blood drawing which will result in a temporary slight discoloration in the skin surrounding it. Some people experience dizziness and/or fainting when blood is drawn. It is important to inform the research staff if you have a history of fainting. The DXA will produce a small amount of radiation which is less than that received during 1 day of background radiation. I may be asked to perform these measurements twice as part of routine quality control for these instruments that will take approximately another 10 minutes. Our intent is to maintain complete confidentiality; however, there is a risk for breach of privacy therefore total confidentiality cannot be assured.

Blood draw:

When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place where your blood is drawn; however, infection is rare.

Interaction with other medications:
You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study coordinator and get permission from the study doctor to continue taking these medicines. You will follow the instructions of the study doctor about the use of any of these products.

You should also tell the study coordinator about all medications that other doctors may have prescribed for you to take in a medical survey form that you will be asked to fill out.

Reproductive Risks of Harm
If you are a woman of childbearing age, you will be asked not to participate in this study.

Are there any benefits to me if I choose to take part in this study?
You will receive information about your blood levels of glucose and lipids, and body composition at your final visit (or sooner upon request) that you can share with your physician. Another benefit is that you will receive monetary compensation at your final visit. There are no other benefits from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
We will not give you any individual results from the study test meals since this is assessed after the full study ends. If we find something of urgent medical importance in your screening laboratory blood report, we ask you to inform your own physician and depending on the finding you may be considered ineligible for further participation in the study. On the last test day, you will receive a report of your findings of your body composition, and laboratory screening. Overall, these tests are done for research purposes only and not for health analysis nor clinical care.

Will there be any cost to me to take Part in this study?
Measurement and analysis of body composition, blood glucose, lipid levels and liver function tests, and other blood markers will be performed at no cost to you whether or not you continue participation in the study.

Will I be paid to take part in this study?
You will receive up to $180.00 at the end of this study according to the following schedule:

- $ 50.00 for completing the first breakfast meal/test day.
- $ 130.00 for completing the second breakfast meal/ test day

If you are unable to complete this study, you will receive a prorated amount based on when you withdraw.

How will information about me be kept private or confidential?
Your research records will be kept strictly confidential to the fullest extent permitted by law. All records are kept in a locked cabinet and/or on a locked computer that requires a password located in locked rooms only available to the research staff conducting the study. All data will be coded and stored with ID numbers, not

names, and this de-identified data with ID numbers will be stored separately from where identifying information is stored in Foran Hall at Rutgers (key access only). In addition, blood samples are kept in a locked freezer, and the cabinets, computers and freezers are within the principal investigator's locked lab to ensure subject confidentiality. Only researchers who are trained on issues of confidentiality and who human certification training will have access to files. Your name will not be used in any reports or publications. Research records will not be released to your private physician without prior consent. Monitors from the IRB and federal regulatory agencies may need to see your research records to help ensure that the rights and welfare of the research participants are protected and that the study is carried out in an ethical manner. All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

What will happen to my information or biospecimens collected for this research after the study is over?
After information that could identify you has been removed, de-identified information (blood samples, body composition scans) collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

What will happen if I am injured during this study?
For Research on Subjects: Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include consumption of a moderately high fat meal and/or food-derived endotoxin. In addition, it is possible that during the course of this study, new adverse effects of food-derived endotoxin and/or moderately high fat intake that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Sue Shapses, PhD Foran Hall, 59 Dudley Rd, New Brunswick, NJ 08901

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop protocol even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish for more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Sue Shapses, PhD, Department of Nutrition Sciences at 848-932-9403.

If you have questions, concerns, problems, information, or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Office at: (973) 972-3608 or (732) 235-

9806 or (732) 235-2866, or email us at IRBOffice@research.rutgers.edu, or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

Will I Be Able to Review My Research Record While Research Is Ongoing?
Yes, for any clinical standard blood measurements (such as glucose and lipids), you can request it or you will receive it automatically during your visit (hard copy) at the end of the ~1-month study. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have to Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind and Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Sue Shapses, PhD, 59 Dudley Rd, New Brunswick, NJ 08901.

How Long Will My Permission Last?
Your permission for the use and sharing of your health information has no set end date. Your health information may be studied for many years, but your identity will be removed in the analysis.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____