Department of Nutritional Sciences

CONSENT FORM

Postprandial Lipemia as a Screening Tool for People with Nonalcoholic Fatty Liver Disease

IMPACT OF COVID-19 ON THIS STUDY

Although temporarily paused due to COVID-19, this study has been permitted to resume.
At the present time, there is increased risk of COVID-19 exposure with all activities located outside of your personal residence.
However, the researchers are committed to strong measures to lessen risk of COVID-19 spread during your participation in this study.

Should you choose to participate in this study, the following steps will be taken to decrease risk of COVID-19 spread:

- All participants will be screened via telephone prior to attending the laboratory.
- Temperature checks will be conducted on all researchers and participants upon entering the laboratory.
- All individuals will apply hand sanitizer and wear a mask upon entering the laboratory. Researchers will wear a mask, gloves and a laboratory coat.
- If you participate, you will be the only participant in the laboratory and there will never be more than 2 investigators in the laboratory with you.
- As much as possible, individuals in the laboratory will be at least 6 feet apart.
- Investigators will wash their hands or apply hand sanitizer before and after every procedure during your assessment.
- Prior to your arrival in the laboratory, all surfaces that you will contact will be disinfected. This will be repeated after each participant leaves the laboratory. We will also disinfect equipment after each specific test/procedure.

Background Information

You are invited to participate in a research study assessing the associations between postprandial lipemia and nonalcoholic fatty liver disease (NAFLD). Considering that NAFLD is characterized by the accumulation of fat in the liver and that people with NAFLD exhibit impaired fat metabolism and ability to clear fat after a high-fat meal, our Abbreviated Fat Tolerance Test (AFTT) may be a more useful screening tool when compared to traditionally-used NAFLD screening tools and may allow for earlier, more sensitive detection of NAFLD. Overall, the goal of the study is to determine if people with NAFLD exhibit an impaired ability to clear fat in the post-meal period following the consumption of a high-fat meal. We ask that you read this form and ask any questions you may have before agreeing to be in the study. Your participation is entirely voluntary.

To be eligible to participate in this study you must fall into at least one of the categories below:

- **Adult with diagnosed NAFLD (confirmed by physician)**
  - Age 18-70 years
  - Any body composition is eligible

Regardless of category above, to be eligible you must not:

- Consume more than 2 alcoholic beverages/day for men and more than 1 alcoholic beverage/day for women
- Be pregnant
- Use drugs, such as calcium channel blockers
- Currently on hormone-replacement therapy
- Be a current smoker

This study is being conducted by: Christina Sciarrillo, Department of Nutritional Sciences, Bryant Keirns, Department of Nutritional Sciences, Kara Poindexter, Department of Nutritional Sciences; under the direction of Sam R Emerson, PhD, Department of Nutritional Sciences.

Procedures

***Overview of Study*:** If you participate, you will report to the laboratory on two occasions: an initial assessment and a meal assessment. The initial assessment will consist of paperwork (informed consent, health history questionnaire, physical activity questionnaires, 3-day food record, and a food frequency questionnaire), height and weight/body composition measurement, and blood pressure.

The second appointment will consist of the meal tolerance test and vascular function assessment. Both of these procedures are described in detail below. You will arrive in the lab having followed a 10-hour fast. You will first undergo a non-invasive vascular function assessment. You will then undergo a meal tolerance test. In brief, a fasting blood draw is made via single venipuncture. Next, you will consume a hypo-allergenic milkshake (described in detail below). You are then free to leave the laboratory for several hours.

You will return 4 hours later for a follow-up blood draw and vascular function assessment to determine your post-meal metabolic and vascular responses.

***Specific Procedures*:**

Blood pressure: We will measure your blood pressure using an automatic cuff on the upper-arm 2-3 times.

Body composition: We will measure your body composition using a Seca mBCA 514. The Seca uses a non-invasive technique called bio-electrical impedance analysis (BIA), which works by sending a small, insensible electrical current through your body and measuring the flow resistance of the electrical current based on different tissues. The Seca also has a weight scale integrated into the system, so we will measure weight simultaneously.

Physical activity assessment: You will be administered and asked to complete a questionnaire pertaining to your current physical activity habits.

Dietary assessment: You will be administered and asked to complete a 3-day food record, related to recent dietary intake, and a food frequency questionnaire on your dietary habits relating to the amounts of and frequency of foods you consume.

AFTT: We will measure the post-meal circulating lipid (fat) response using an AFTT. You will come into the lab fasted. First, we will collect a fasting/baseline blood draw using single needle stick (described below). You will then eat the gluten-free, dairy-free, high-fat test meal (milk shake consisting of coconut milk, chocolate syrup and protein powder; 70% fat; ~9 kcal/kg). After completing the test meal, you will be instructed to leave the lab for ~4 hours, abstaining from additional food intake or planned exercise. You will then return for a follow-up blood draw 4-hours after meal completion.

Flow-mediated dilation via Doppler ultrasound imaging: We will measure vascular function using a technique called flow-mediated dilation. This test will be conducted when you come into the lab fasted for your meal tolerance test, and again at follow-up (4-hours after meal consumption). An ultrasound probe will be used to image your brachial artery. We will collect baseline video imaging for 4 minutes. We will then use a pediatric blood pressure cuff to occlude blood flow at the wrist for 4 minutes. The pressure of the blood pressure cuff will be approximately 50 mmHg above your systolic blood pressure. We will then release of the blood pressure cuff to induce an increase in blood flow. The degree of vascular dilation is indicative of vascular health. We will continue to image the blood vessel to measure this dilation for 4 minutes after the cuff is released.

Phlebotomy (single needle sticks): A 21-gauge needle will be used to draw blood from a forearm vein at baseline and 4 hours post-challenge for the AFTT. We will draw approximately 4 mL of blood each time. Therefore, we will draw a total of ~8 mL over the course of the study.

Participation in the study involves the following time commitment:
Initial assessment: 30 minutes
AFTT: 5 hours (although you will not be in the lab for the vast majority of this time), includes vascular function assessment
Total time commitment for study: 5.5 hours
Total time commitment for study in the laboratory: ~1.5 hour

Biospecimen Sampling for Research:
We will be collecting blood samples to measure metabolic markers in circulation.

The type of specimens that will be stored and where they will be stored: No biospecimens will be stored. All blood samples will be analyzed immediately and then discarded.

Risks and Benefits of Study Participation

The only foreseeable risks involved in this study are related to phlebotomy (single needle sticks) and flow-mediated dilation (measurement of blood vessel function). These risks are described in the dedicated section below. In order to assist with the offset of these risks, we are utilizing the most participant-friendly procedures possible to address our research aims: we are conducting the minimal amount of needle sticks, drawing the minimal amount of blood, and inflating the wrist cuff for flow-mediated dilation to the lowest possible pressure to still produce the necessary response. In case of injury or illness resulting from this study, emergency medical treatment will be available through transportation to the nearby student health center or hospital. However, this outcome is highly unlikely. No funds have been set aside by Oklahoma State University to compensate you in the event of illness or injury.

Phlebotomy/Single Needle Sticks:
Risks of phlebotomy include slight pain/discomfort upon needle insertion, and potential redness and bruising at the site of the insertion. A blood draw may lead to lightheadedness or fainting in some individuals. In order to minimize these risks, we will wipe the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising. To protect against infection, we will also provide instructions on how to care

for the puncture site and watch it for signs of infection. It is important to know that these blood tests performed in the study are strictly for research purposes. The researcher using your blood sample is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these blood tests, as the researchers are not using this test to make a diagnosis.

Flow-mediated Dilation:
The process of occlusion (i.e. restricting blood flow) will cause a numb feeling, which may be perceived as discomfort or pain. The feeling is similar to that of your arm or leg "falling asleep". When the cuff is released, the return of blood flow will create a warm sensation. Overall, the occlusion of blood flow does not present more than minimal discomfort to participants.

The benefits to participation are: Your metabolic, vascular function, and body composition results will be shared with you. Some individuals find this personal health information very interesting. However, we cannot guarantee or promise that you will find this study or its associated information beneficial.

Compensation
You will receive no financial compensation for your participation in this study.

Confidentiality
The information that you give in the study will be handled confidentially. Your information will be assigned a code number. Your name will not be used in any report.

We will collect your information through paper surveys and metabolic assessments. Paper surveys and data sheets will be stored in a locked filing cabinet in a locked laboratory. Data will be stored electronically on a password-protected program on a password-protected laptop that does not leave the locked laboratory, and backed up on an encrypted and password-protected external hard drive. This informed consent form will be kept for 3 years after the study is complete, and then it will be destroyed. Your data collected as part of this research project, will not be used or distributed for future research studies.

It is unlikely, but possible, that others responsible for research oversight may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

Voluntary Nature of the Study
Your participation in this research is voluntary. There is no penalty for refusal to participate, and you are free to withdraw your consent and participation in this project at any time. The alternative is to not participate. On the questionnaires, you can skip any questions that make you uncomfortable and can stop at any time.

Contacts and Questions
The Institutional Review Board (IRB) for the protection of human research participants at Oklahoma State University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at 405-744-2303, sam.emerson@okstate.edu. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the IRB at (405) 744-3377 or irb@okstate.edu. All reports or correspondence will be kept confidential.

You will be given a copy of this information to keep for your records.

Statement of Consent
I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Indicate Yes or No:

I give consent to be contacted for follow-up in this study or future similar studies:
___Yes ___No

Signature: _____ Date: _____