University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research

Effects of acute aerobic exercise intensity on plasma sRAGE in lean healthy individuals

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: **Jacob M. Haus, Ph.D., Assistant Professor**

Department and Institution: **Department of Kinesiology and Nutrition, at the University of Illinois at Chicago**

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Emergency Contact Name and Information: **Jacob Haus, phone: (330) 518 – 8225**

Sponsor: **none**

Why am I being asked?

You are being asked to be a subject in a research study about how different aerobic exercise intensities change the amount of a beneficial protein that is found in your body.

You have been asked to participate in the research because you have responded to an advertisement and are interested in being a participant

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 20 subjects may be involved in this research at UIC.

What is the purpose of this research?

A protein found in the body called sRAGE (soluble receptor for advanced glycation endproducts) may play a protective role in the development of future disease. Exercise has been shown to increase the amount of this protein in your body. This study is being done to find out if exercise intensity plays a role in the extent at which these protein level changes occur.

What procedures are involved?

This research will be performed at the Integrative Physiology Laboratory in the Disabilities, Health and Social Policy Building (DHSP) at 1640 W. Roosevelt Rd.

You will need to come to the study site at 4 separate times (4 study visits).

The total time of these combined visits is estimated to be approximately 10-11 hrs.

The study procedures are as follows:

VISIT 1:

For this visit you will be asked to report to the Integrative Physiology Laboratory in the Disabilities, Health and Social Policy Building (DHSP) at 1640 W. Roosevelt Rd.

This visit must be performed in the morning. This visit will be comprised of the procedures listed below. The total time for completing this visit is expected to be about *2 hrs*.

We ask that you fast for a period of 10-12 hrs prior to this visit and that you refrain from consuming alcohol for 48 hrs prior to participating in this study.

You will read and sign two copies of this informed consent document in order to enroll in the study. A study team member go through the informed consent document in detail with you, answering any questions you may have relating to the study. Once this document has been read and signed, confirming that you understand the study, you will be enrolled. Then, these procedures will occur in the following order.

- A study team member will take your height and weight
- *Dual Energy Absorptiometry (DEXA)* (approximately 30 minutes): This test is used to measure the amount of fat distributed throughout your whole body and will allow us to measure your percent body fat. During this test, you will lay on your back on a table for 10-15 minutes while a scanner passes over your body. This test also involves a very small amount of radiation exposure.

- *Blood Draw*: We will collect blood samples *two times* during this visit. The total amount of blood we will take from you is about 20 cc or 1 tablespoon. The first blood draw will be taken before the exercise capacity test (below) and the second blood draw will be taken after the exercise capacity test.

- *Exercise Capacity test* (approximately 30 minutes): This test will be used to evaluate your current level of physical fitness. You will be encouraged to walk on a treadmill as much as you can, safely. During this test you will breathe into a mouthpiece and a clip will be placed over your nose so that all of the air you breathe in and out, will pass through the mouthpiece and into a machine alongside the treadmill. The machine allows us to measure your oxygen consumption and provides a measure of your maximum oxygen capacity (VO2max), or maximum exercise capacity. During this test your heart rate and feelings of how hard you are working will also be monitored. You will walk or jog on a treadmill, with the incline progressively increased every few minutes, until fatigue, breathlessness, and/or symptoms indicate to the research staff, or yourself, that you should stop the exercise.

- *Questionnaires*: Following the procedures described above you will be given 2 separate questionnaires and instructions for their use on how to record your eating and physical activity habits. You will be asked to complete each of these questionairres for every day until the next study visit.

VISIT 2:

Approximately 4 days after *visit 1* or when your schedule permits you will be asked to return to the Integrative Physiology Laboratory in the Disabilities, Health and Social Policy Building (DHSP) at 1640 W. Roosevelt Rd.

This visit must be performed in the morning. This visit will be comprised of the procedures listed below. The total time for completing this visit is expected to be about *2 hrs*.

We ask that you fast for a period of 10-12 hrs prior to this visit and that you refrain from consuming alcohol for 48 hrs prior to participating in this study.

- *Blood Draw*: We will collect blood samples *three times* during this visit. The total amount of blood we will take from you is about 30 cc or 1.5 tablespoons. The first blood draw will be taken before the low intensity exercise test (below), the second blood draw will be taken during the exercise test and the final blood draw will be taken after completing the exercise test

- *Low Intensity Exercise Test* (approximately 60 minutes): During this visit you will perform treadmill exercise at low intensity (40% of your maximum capacity) for one hour. During this test you will breathe into a mouthpiece and a clip will be placed over your nose so that all of the air you breathe in and out, will pass through the mouthpiece and into a machine alongside the treadmill. The machine allows us to measure your

oxygen consumption and provides a measure of your metabolism. During this test your heart rate and feelings of how hard you are working will also be monitored.

- *Questionnaires*: Following the procedures described above you will be given 2 separate questionnaires and instructions for their use on how to record your eating and physical activity habits. You will be asked to complete each of these questionnaires for every day until the next study visit.

VISIT 3:

Approximately 4 days after *visit 2* or when your schedule permits you will be asked to return to the Integrative Physiology Laboratory in the Disabilities, Health and Social Policy Building (DHSP) at 1640 W. Roosevelt Rd.

This visit must be performed in the morning. This visit will be comprised of the procedures listed below. The total time for completing this visit is expected to be about *2 hrs*.

We ask that you fast for a period of 10-12 hrs prior to this visit and that you refrain from consuming alcohol for 48 hrs prior to participating in this study.

- *Blood Draw*: We will collect blood samples *three times* during this visit. The total amount of blood we will take from you is about 30 cc or 1.5 tablespoons. The first blood draw will be taken before the moderate intensity exercise test (below), the second blood draw will be taken during the exercise test and the final blood draw will be taken after completing the exercise test

- *Moderate Intensity Exercise Test* (approximately 60 minutes): During this visit you will perform treadmill exercise at moderate intensity (65% of your maximum capacity) for a period of time that equals the energy you burned during the *visit 2* exercises test. During this test you will breathe into a mouthpiece and a clip will be placed over your nose so that all of the air you breathe in and out, will pass through the mouthpiece and into a machine alongside the treadmill. The machine allows us to measure your oxygen consumption and provides a measure of your metabolism. During this test your heart rate and feelings of how hard you are working will also be monitored.

- *Questionnaires*: Following the procedures described above you will be given 2 separate questionnaires and instructions for their use on how to record your eating and physical activity habits. You will be asked to complete each of these questionnaires for every day until the next study visit.

VISIT 4:

Approximately 4 days after *visit 3* or when your schedule permits you will be asked to return to the Integrative Physiology Laboratory in the Disabilities, Health and Social Policy Building (DHSP) at 1640 W. Roosevelt Rd.

This visit must be performed in the morning. This visit will be comprised of the procedures listed below. The total time for completing this visit is expected to be about *4 hrs.*

We ask that you fast for a period of 10-12 hrs prior to this visit and that you refrain from consuming alcohol for 48 hrs prior to participating in this study.

- *Blood Draw*: We will collect blood samples *four times* during this visit. The total amount of blood we will take from you is about 40 cc or 2 tablespoons. The first blood draw will be taken before the high intensity exercise test (below), the second blood draw will be taken during the exercise test, the third blood draw will be taken immediately after completing the exercise test and the final blood draw will be taken 3 hrs after completing the exercise test.

- *High Intensity Exercise Test* (approximately 30-40 minutes): During this visit you will perform treadmill exercise at high intensity (80% of your maximum capacity) for a period of time that equals the energy you burned during the *visit 2* exercises test. During this test you will breathe into a mouthpiece and a clip will be placed over your nose so that all of the air you breathe in and out, will pass through the mouthpiece and into a machine alongside the treadmill. The machine allows us to measure your oxygen consumption and provides a measure of your metabolism. During this test your heart rate and feelings of how hard you are working will also be monitored.

- *Muscle Biopsy* (approximately 1.5 hrs): We will collect muscle biopsy samples three times during this visit. The first muscle will be taken before the high intensity exercise test, the second muscle biopsy will be taken immediately after completing the exercise test and the final muscle biopsy will be taken 3 hrs after completing the exercise test.

  The biopsy involves removal of a very small piece of muscle (1/3 the size of an eraser on a pencil) by inserting a needle into your outer thigh muscle through a quarter inch skin incision. Local anesthesia will be used to numb the area where the incision will be made. Muscle biopsies will be performed on both legs, alternating right and left. The biopsy involves the following:

  First, the skin on the outside portion of your lower thigh will be cleansed with an cleaning solution to sterile the area. Once thoroughly cleansed and dry, a small amount of numbing agent (about 3-4 cc, or less than ½ teaspoon of Lidocaine), will be injected into the area to be biopsied. If you are allergic to Lidocaine or drugs in the 'caine' family (e.g., Novocaine), tell the research team.

  Once the area is sufficiently numbed, a small incision will be made (approximately 5 mm, or less than ¼ of an inch) and a biopsy needle will be inserted in order to obtain approximately 200 mg per biopsy (400mg total) or about 0.007 ounces of muscle per biopsy. Once the biopsy has been completed, slight pressure will be applied to the biopsy area to minimize any bleeding. The area will then be cleansed and a special bandage will be applied to the biopsy site. An ACE bandage will be wrapped over the

site and you will be asked to wear this bandage for the next 24 hours to reduce the risk of bleeding.

One of the study team members will call you within 24 hours to follow-up on how your biopsy is healing and to ask if you are having any pain or discomfort that might limit your activity.

- After completion of the final muscle biopsy, you will have completed the study.

Tissue Banking and Participating in Future Studies

We would like to save tissue left-over after your muscle biopsy is tested to be used in future research. This excess tissue may be used to further explore mechanisms, which may contribute to the development of diabetes. Samples will be de-identified, and stored in the PI's laboratory to which only he and his personnel have access. Samples will be stored until utilized.

☐ I agree to allow my tissue sample to be kept by **Jacob Haus, PhD** for use in future research to learn more about how to prevent, detect, or treat disease.

☐ I do not agree to allow my tissue sample to be kept by **Jacob Haus, PhD** for use in future research to learn more about how to prevent, detect, or treat disease.

Initials _____

We plan future studies about how the body uses energy and stores fat. We would like to be able to contact you about future studies. Please indicate your interest about being contacted for future studies.

☐ I agree to allow the researchers to contact me about future research studies.

Initials_____.

How Long Will I Be In The Study?

Your participation in this study will last approximately 12 days and you will be asked to visit the west campus of University of Illinois at Chicago 4 times depending upon your schedule. The time required for these visits will vary depending upon the specific tests performed but we estimate that the total time required will be about 10-11 total hours.

What are the potential risks and discomforts?

Your participation in this study may involve the following risks:

Blood Draw: The risks of drawing blood from a vein includes discomfort at the site of the needle stick, possible bruising and swelling around the site of the needle stick, rarely an infection, and uncommonly feeling faint from the procedure.

Muscle Biopsy: You will feel pain, cramping, or bleeding where the sample is taken. Infection is very rare as your skin is cleansed with alcohol and the needle used is sterile. It is very rare, but you could have an allergic reaction to the lidocaine that is used to numb your skin. Tell the research team if you are allergic to any drugs in the "-caine" family (for example, lidocaine, novocaine).

Activity is good for your muscle after the biopsy. Walking is required after the biopsy procedure to help prevent additional stiffness and blood clot formation. (The development of a blood clot is related to inactivity, and may occur in less than 1% of biopsy procedures).

There may be additional pain at the biopsy site during or after exercise and there is also a possible risk of scarring.

Exercise capacity test/High intensity exercise: With a maximal effort exercise tests such as a VO2MAX there is an inherent risk of complications such as chest pain, shortness of breath, dizziness and rarely heart attack. However the occurrence of such events is highly unlikely in younger lean healthy individuals such as those who will be recruited for this study. You will be constantly monitored by exercise professionals who are CPR and advanced cardiac life support (ACLS) certified and will terminate any of the exercise trials at any time if they should feel it necessary. The apparatus/mask and nose clip used to measure VO2max may make you uncomfortable.

Exercise testing on the treadmill: You might experience tiredness or shortness of breath. You might feel like your heart is pounding very fast or very hard. You might feel dizzy or experience chest pain. You could stumble and fall off the treadmill. If you have any of these experiences, tell the research team. Also, when the breathing tube is in your mouth and you are wearing the nose clip, this might feel uncomfortable.

Radiation Exposure from DEXA scan: One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer in the U.S. is about 1 chance in 5. Everyday radiation exposure from natural occurring background radiation (sun, radon exposure in the home) is approximately 3.0 mSv per year. In this research study, you will be receiving a DEXA scan. One DEXA scans amount to 0.6 mSv. The total radiation exposure in this study is about 0.6 mSv which is equal to approximately 0.2 years' worth of natural radiation exposure. This amount of radiation is very low as to make an accurate risk estimate meaningless. There is also no chance for skin injury. If you have already had many x-rays you should discuss the potential added risk from more radiation with the researchers before agreeing to be in the study.

Pregnant women, fertile females/males: There may be unforeseen risks to an unborn child associated with some of the study testing. Therefore, if you are capable of giving birth to or fathering a child, you and your sexual partner should use adequate birth control measures while you are in the study. These measures may include abstinence, oral contraceptives (birth control pills), IUD, diaphragm, approved hormone injections, condoms, or documentation of medical sterilization. If you are unwilling to do this, we ask that you not participate in this study.

Pregnancy tests will be performed on all women of child-bearing potential before beginning the study and before each DEXA scan. If you or your spouse becomes pregnant while taking part in this study you must notify the research staff immediately.

Questionnaires: You might find it boring or time-consuming to complete the questionnaires. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable.

Dietary restrictions: You may find it burdensome to adhere to abstain from eating or drinking food or drink items containing caffeine or alcohol during the study periods. You might have to fight cravings to eat or drink items that are not permitted.

Unforeseeable risks: There may be risks or side effects related to the study that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

Loss of Confidentiality: There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

Will I be told about new information that may affect my decision to participate?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled.

Are there benefits to taking part in the research?

You will not benefit from participating in this research

What other options are there?

You have the option to not participate in this study.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent/authorization form signed by you will be looked at and/or copied for examining the research by:

- UIC Office for the Protection of Research Subjects, and State of Illinois Auditors

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research.

Personal information collected will be kept secure by the investigative team in locked file cabinets in a controlled access room. Once you enroll into the study your name will be given a special code and then we will no longer use your name or personal information to identify the data we collect from you. Only the principal investigator will have access to the coded information

The final information collected from you will be stored in a secured manner as mentioned above to protect your information and ensure your privacy

At the completion of the study, any documents with personal information will be stripped of any information that can identify you only the coded data will remain. We will keep the coded information until we no longer need this information or until this information is of no further benefit in the discovery for the mechanisms and treatment of disease.
When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

What if I am injured as a result of my participation?

You may have medical problems or side effects from taking part in this research study. If you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through:

- The UIC Medical Center OR
- Your regular doctor OR
- The treatment center or clinic of your choice.

If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You may contact the researcher, **Jacob Haus, PhD at (330)-518-8225,** to talk to them about your illness or injury or in the case of an emergency.

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for the University to provide free medical care or to pay for research-

related illnesses or injuries, or for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

By signing this form you will not give up any legal rights.

What are the costs for participating in this research?

There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will be compensated $100 for completion of the study. Payments will be disbursed in 4 installments. You will receive $25 following completion of each visit. Compensation will not be provided for visits that you do not complete should you withdraw from the study.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC.

The researchers also have the right to stop your participation in this study without your consent if:

- You fail to follow the instructions of the study doctor or study staff.
- The study doctor decides that continuing participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.

In the event you withdraw or are asked to leave the study, you will be compensated as described above.

Who should I contact if I have questions?

Contact the researchers **Jacob M. Haus, PhD, Assistant Professor of Kinesiology and Nutrition at 312-413-1913 or email address: hausj@uic.edu**

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- if you have questions, concerns or complaints about the research.

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent