The Acute Effect of Moderate Intensity Stair-Climbing on Postprandial Blood Glucose

NCT Number: Not assigned yet

February 24, 2016

SAN DIEGO STATE UNIVERSITY

Informed Consent Form

Consent Form Version Date: January 24, 2016

Short Stair Climbing Bout after Glucose Drink…

Conducted by Dr. Jochen Kressler and Tracie Wymer, B.S.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

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WHAT IS THE PURPOSE OF THIS RESEARCH:

The purpose of this study is to investigate the effect of light to moderate stair walking on blood sugar levels after drinking a glucose drink. We will be taking blood samples from your finger-tips using a glucometer to test blood sugar levels every 15 minutes for 1 hour. Two additional blood samples will be taken from your forearm vein one time prior to consumption of the drink and one time 30 min thereafter. The blood draws allow us to collect more blood and analyze for additional markers such as insulin and markers of inflammation. We will measure heart rate using a heart rate monitor to ensure exercise is being performed at the correct level. 30 participants will be involved in the study taking place at San Diego State University.

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HOW LONG WILL I BE IN THIS RESEARCH?

Your participation will last one to three weeks. You will come to SDSU for 5 visits each lasting between 1-1.5 hours.

WHAT WILL HAPPEN IN THIS RESEARCH?

To determine if you are eligible to participate, you will be asked to complete a questionnaire about your health history. If your responses indicate you are eligible you will be asked to participate. If you are not eligible to participate, the information obtained during the screening will not be included in the study data and the screening questionnaire will be shredded to protect your privacy.

If you decide to participate, you will come to the laboratory 5 times. Each visit will last about 60-90 minutes. They will be scheduled at least 1 day but no more than 1 week apart.

During the first visit you will complete the informed consent form, health screening, and a maximal exercise test in the ENS Annex exercise physiology laboratory (ENS 102). The maximal exercise test will take place on a treadmill. You will begin by walking at a slow speed with no incline. Every 3 minutes following the initiation of the test, the speed and incline will be increased until you are exercising as hard as possible cannot go any further. During this test, you will be wearing a nose clip and breathing through a mouthpiece into a hose, which is

connected, to a machine that analyzes air you breathe out. After a recovery period following the exercise test, we will show you the staircase (32 steps) you will use during the study. You will have an opportunity to determine a stair stepping speed that will be comfortable for you to complete up to 10 minutes of stair exercise (up and down).

On the second visit through the 5th visit your participation will start with a glucose tolerance test. If your glucose levels are outside the target by the American Diabetes Association (80-130 mg/dL) we will have to stop your participation in the study and we will recommend discussing this with a health care professional. You can check the American Diabetes Association guidelines under this link http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/checking-your-blood-glucose.html. To prepare for this study you will not eat after 10 pm the night before until you arrive in the lab. You will also not exercise for 24 hours prior to each visit. We ask that you to try to eat either the same or a similar meal the night before every visit. When you arrive in the lab, you will be fitted with a heartrate monitor that you will wear throughout your visit. You will drink 75 g (2.6 oz or about 5 tablespoons) of sugar dissolved in 2 cups of water within 5 minutes then sit quietly for 1 hour. You will be allowed to read or watch videos or similar activities. The investigators will sample blood from a small finger stick before you drink and every 15 min after you finish the drink for one hour (5 samples of blood). The investigators will also take two blood draws from a forearm vein. One before the sugar drink and one 30 minutes after you finish the drink.

On visits 3-5 you will follow the same steps to prepare for your visit, drink the same sugar drink and have the same blood draws as on visit two. In addition, you will also walk up and down the 32 stairs (at the speed you determined on day 1) for either 10 minutes, 3minutes or 1 minute. Depending on how long you will be stair climbing, you will start climbing 15, 22 or 24 minutes after you finish the drink. While stair-climbing, you will be wearing the heart rate monitor around your chest, to determine how hard you are working. You will also wear a breathing mask like the one you used for the exercise test on visit one starting 5 minutes before you begin climbing the stairs and continuing until 15 minutes after your climbing ends. Your breathing mask will be attached to a much smaller and lighter machine, which you can wear like a small backpack, during the stair climbing.

Below is a table with an overview of your 5 laboratory visits.

	Visit 1	**Visit 2**	**Visit 3-5**
Health/medical history questionnaire	X		
Glucose Tolerance Test	X	X	X
Breathing Mask Exercise	Maximal Exercise Test		Stair climbing
Finger Prick blood sampling (5 samples)		X	X
Blood Draw (2 samples from vein)		X	X
Stair Walking (10, 3 or 1 minutes)			X
Total time	1 hour and 20 minutes	1 hour and 15 minutes	1 hour and 5 minutes

Finger stick blood testing will be done with a small lancet and measured with a glucometer 5 times each visit. The total amount of blood drawn with finger sticks will be less than 1/1000th of a teaspoon.

There will also be 2 blood draws from a forearm vein. The total amount drawn here is 2*5 mL = 10 mL which is about 2/3 of a tablespoon.

None of the procedures used in this study are experimental in nature. Lancets and glucometers are commonly used by people with diabetes when checking blood sugar levels. The blood draws will be performed by a licensed phlebotomist. The only experimental aspect of this study is the gathering of information for the purpose of analysis.

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

Overnight Fast: You are being asked to fast (refrain from eating) a minimum of 10 hours prior to testing. This means for an 8:00am test you would stop consuming all foods and beverages (besides water) at 10:00pm the previous night. The risks associated with this may include light-headedness and/or fatigue. Hunger may make you uncomfortable while fasting.

Oral Glucose Tolerance Test (OGTT): You are being asked to consume 75 grams of sugar (glucose) on an empty stomach for this test. Minimal risks are associated with OGTT but nausea may occur when drinking the beverage.

Exercise Tests: You are being asked to perform exercise that may lead to minor physical discomfort (e.g. fatigue or muscle soreness). Very rarely, maximal exercise testing can lead to cardiovascular complications (less than 1:12,000 healthy subjects).

To minimize these risks, our laboratory is equipped with an automated defibrillator and at least one member of the research team is CPR certified. If at any time during the maximal exercise test you want to stop, you can signal us and we will stop the test. You will feel very tired at the end of the test, but should recover within a few minutes. Your heart rate will be monitored throughout the exercise bout and you will be instructed to stop if your heart rate reaches 85% of your maximum heart rate as determined by your age.

Finger Prick: This study involves 5 finger pricks at each lab visit. You may feel some pain from the lancet when your blood is drawn. There is a small chance the lancet will cause a bruise or, in rare cases, an infection.

Forearm Blood Draws: This study involves ~~a~~ two blood draws at each lab visit. A Nationally Certified Phlebotomist will perform blood draws. You may feel some pain from the needle when your blood is drawn. There is a small chance the needle will cause a bruise or in rare cases an infection. You may also feel lightheaded. If you faint, we will position you on your back on the floor. The researcher may lift your legs to help circulate your blood. If you ~~s~~hould stop breathing, a CPR certified research team member will administer CPR and 911 will be called.

Unknown and Unforeseeable Risks: In addition to the risks listed above, there may be some unknown risks related to the study procedures. We will tell you as soon as we know about any new risks or changes to the way the research will be performed that might influence your willingness to take part in this study.

For more information about risks and side effects, ask either of the lead researchers.

ARE THERE ANY BENEFITS TO PARTICIPATION?
You will learn about your blood sugar levels and blood sugar spike after drinking a sugar drink.

By participating you are helping to discover new information on how exercise duration can alter blood sugar rising after drinking a sugar beverage.

ARE THERE ANY ALTERNATIVES TO PARTICIPATION?
An alternative is to not participate.

WILL MY INFORMATION BE PRIVATE?
Confidentiality will be maintained to the extent allowed by law.

Research records will be stored in a locked office in a locked file cabinet and will only be accessible to research staff listed on the first page of this consent form. Research data will be destroyed at least three years after the end of this study. During the study, only the lead researcher and other members of the research team will have access to the data. Further, no personally identifiable data will be disclosed to anyone other than the research team without your written consent.

The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you.

WHAT WILL HAPPEN IF I AM HURT OR INJURED?

If any complications arise as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. San Diego State University will not pay for any care, lost wages, or provide other financial compensation [include San Diego State University Foundation if this research is funded]. However, if you feel you have a claim that you wish to file against the State [or the Foundation], please contact Graduate and Research Affairs - Division of Research Administration at (619) 594-6622 to obtain the appropriate claim forms.

DO I HAVE TO PARTICIPATE?
You do not have to participate in this research study. If you choose not to participate there is no penalty or loss of benefits to which you are otherwise entitled. Additionally, you may choose to stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.
If you choose to terminate participation in this study, your data will be kept but will be unidentifiable to everyone other than the primary investigator. Data will be processed and destroyed at least three years after the end of the study.

WILL I BE TOLD ABOUT THE STUDY RESULTS?

If you ask us we will tell your results from the maximal exercise test after you complete the test.
If you ask us we will also tell you your blood sugar response but we will only do that at the end of your last visit so it does not influence your testing.
We will not contact you with results of this study after this study is completed.
There may be new findings developed during this research, which may relate to your willingness to continue to participate in this study. These new findings will be shared with you. You may contact the lead researchers if you wish to find out more about the results of this study.

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WILL IT COST ME ANYTHING TO PARTICIPATE?

The only cost of this study is your transportation to campus. There will be no financial support for gas, parking passes or public transportation.

WILL I BE PAID FOR MY PARTICIPATION IN THE RESEARCH?

No stipend will be awarded to participants of this study.

WHAT IF I HAVE QUESTIONS REGARDING THIS STUDY?

If you have any questions about the research now, please ask. If you have questions later about the research, you may contact Dr. Jochen Kressler at 619-594-0323. If you have any questions about your rights as a participant in this study, or in the event of a research related injury, you may contact the Division of Research Affairs at San Diego State University (telephone: 619-594-6622; email: irb@mail.sdsu.edu). At any time during the research you can contact the IRB for questions about research rights, to discuss problems, concerns, or suggestions, or to offer input.

CONSENT TO PARTICIPATE:

The San Diego State University Institutional Review Board has approved this consent form, as signified by the Board's stamp. The consent form must be reviewed annually and expires on the date indicated on the stamp.
Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you have about the study. Your signature also indicates that you agree to be in the study and have been told that you can change your mind and withdraw your consent to participate at any time. The investigator or a member of his/her research team has provided you with a copy of this consent form with information about whom to contact in the event you have questions.

Name of Participant (please print)	Date
Signature of Participant	Date
Signature of Investigator	Date