Spot Sticks to Measure 24-hour Urine Sodium

We are looking for men and women of all ages to take part in a study examining the accuracy of spot urine samples to 24-hour urine sampling to help validate a method for measuring urine sodium (salt).

Your participation will help improve our understanding of the accuracy of spot samples in comparison to 24-hour urine sodium sampling.

As a thank you for your participation, all participants will receive $20 in compensation.

Your participation in this study will involve recording 5 spot samples over consecutive days. You will also be asked to complete a 24-hour urine sodium collection on the third day.
Are Quantab Chloride sodium test sticks accurate in determining urine sodium concentration?

CONSENT FORM

Principal Investigator: Dr. Victoria Claydon, Associate Professor
Department of Biomedical Physiology and Kinesiology
Simon Fraser University
Vancouver, BC

INVITATION TO PARTICIPATE

In some people who are prone to fainting, their blood pressure is very low and this can be associated with low levels of salt in the body. Measures of body salt content might provide useful information in the care of these individuals. The usual way to measure body salt content is to ask a person to collect all their urine for a 24-hour period, so the salt levels in their urine (which reflects the levels in the body) can be measured. However, for some people the urine collection is inconvenient, particularly in children, and this is a problem because children are very susceptible to fants. We are testing a new method to measure the salt content of the body using test strips that can be done from a single sample of urine in the morning. You are invited to participate in a research study designed to figure out whether this alternative method of analyzing urine for sodium concentration is accurate. The purpose of this form is to provide you with information to help you make an informed decision about whether or not to participate in this research study.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study, and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

Please take time to read the following information carefully and to discuss it with anyone you wish. You will have an opportunity to ask the study team any questions you may have about the study.

WHO IS CONDUCTING THE STUDY?

Dr Victoria Claydon, PhD., who is an Associate Professor with the School of Biomedical Physiology and Kinesiology, Simon Fraser University, along with Natalie Heeney and Brooke Hockin (both graduate students in Dr. Victoria Claydon’s Lab), have designed this study together.

HAS THIS STUDY RECEIVED FUNDING?

This research is funded by the Heart and Stroke Foundation of Canada.

WHO CAN I CONTACT IF I HAVE CONCERNS ABOUT THE STUDY?

If you have concerns about your rights as a research participant and/or your experiences while participating in this study, please contact Dr. Jeffrey Toward, Director, Simon Fraser University Research Ethics (E-mail: jtoward@sfu.ca; telephone: 778-782-6593).
WHAT IS THE PURPOSE OF THE STUDY?

The primary purpose of this study is to test whether spot sample test strips can be used instead of 24-hour urine collections to accurately measure body sodium levels.

WHO CAN PARTICIPATE IN THE STUDY?

You are eligible to take part in this study if you are at least 18 years old and able to understand instructions in English. Women should not complete the study urine collections on days when they have, or expect, their menstrual period.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You should not participate if you do not want to.

If you have a current urinary tract infection, you are asked to wait until it has been successfully treated before volunteering for this study.

If you cannot understand enough English to follow instructions and communicate with the testers you cannot participate.

WHAT DOES THE STUDY INVOLVE/WHAT ARE THE PROCEDURES?

For this study you will be asked to complete five urine spot samples, one each morning for five days. You will collect your first morning pee in a container and place one of the test strips provided by the research team in the sample. Once the strip has recorded the concentration, you may dispose of the sample down the toilet and either rinse the cup for the following day or discard the cup and use a different one the next day. The exception to this is on the 4th day, as this first morning void will need to be collected. Each day you will take a photo of the test strip once it has changed colour, and place the used strip in a container provided. We are asking you to take photos of the test strips in case you have difficulty reading the colour change, you lose a strip, or the colour change fades over time. Once you have shown the pictures to the researcher, you can delete them from your device or camera.

You will also be asked to provide a 24-hour urine sample that you will collect on day three. You will be given a large jug in which you will collect all of your pee on day 3. You will then bring this sample to the lab for analysis. The 24-hour urine collection needs to be refrigerated throughout the day. If you are a member of the SFU community, you may store the jug in a fridge in the research lab for convenience. There are washrooms near the lab and you can come and go to add to your sample collection whenever you need to. Alternatively, you can collect the entire sample on a weekend day from the comfort of your home. When you complete the spot sample on the 4th day, you will be asked to add this to the 24-hour sample, or bring it to the lab so we can add it for you.

Once the spot samples and 24-hour sample have been completed, we ask you bring all five spot sticks, the photos you took, and the 24-hour sample back to the lab. You are free to return the 24-hour sample back to the lab as soon as you like once it is collected.

WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

The study is designed with every effort made to ensure the safety, privacy and comfort of participants. Some volunteers may feel uncomfortable or embarrassed with collecting and storing their urine for a day. If you feel this way, you are free to stop the study at any point.

WHAT ARE THE BENEFITS OF PARTICIPATING?

There are no direct benefits to the volunteers; however, it is hoped that through this study a method that can help aid in the diagnosis of fainting will be validated. This may result in earlier diagnosis for affected
patients, as well as potentially provide a cost-effective and quick method for 24-hour urine sodium estimations.

WHAT IF YOU LEARN NEW INFORMATION ABOUT MY HEALTH DURING THE STUDY?

Measures of urine sodium content are not an indication of your health. We do not expect to learn any information about your health during this study. This study will only provide information on the accuracy of methods for testing sodium levels.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT?

You are free to choose not to participate, and if you do volunteer, you are free to withdraw from this study at any time.

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else.

WHAT WILL THE STUDY COST ME?

There are no costs to you for taking part in this study. Free parking will be provided at Simon Fraser University, where you will need to come to collect and return the study materials. As a thank you for taking part, you will receive a $20 honorarium for your time.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected; this means that all your personal information will be kept private. The information collected in the study will be given a unique and random code instead of your name. Research records with your name and personal information may be inspected by the Simon Fraser University Research Ethics Board for the purpose of monitoring the research. However, these individuals are required to keep all information confidential. No records that identify you by name will be allowed to leave the investigators’ research office. We will keep these records for ten years, after which time they will be destroyed.

We plan to make the results of the study public so that doctors and people with fainting spells can learn from the study. This might be in written reports aimed at doctors and scientists, or in patient information leaflets aimed at people who faint and their families. These documents would also be available online. We will also present the results verbally, for example at science conferences or patient education meetings. In all cases, we will make sure that no one could tell who took part in the study (we would not include any names or other information about participants). If you would like to learn about the results of the study when it is finished, please let one of the study team know.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions or desire further information either before or during participation, you can contact Dr. Victoria Claydon at 778-782-8513 or victoria_claydon@sfu.ca.

PARTICIPANT INFORMED CONSENT

I, _________________________________________, (print full name), have received a copy of the consent form. I consent to participation in this study by signing this consent form. I have read and understand all the preceding information describing the study, and all by questions have been answered to my satisfaction. I voluntarily consent to participate in this study.

Signature____________________________________ Date____________________