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INFORMATION AND CONSENT

Title of Study:

Pilot study on the effects of Saskatoon berry on glucose metabolism, insulin resistance, and gut microbiota in healthy human subjects

Research Study Team

Name	Organization/Affiliation	Role
Garry Shen, MD, PhD	Internal Medicine, University of Manitoba	Endocrinologist, Principal Investigator
Amy Leung Hui, RD, PhD	Internal Medicine, University of Manitoba	Research Coordinator

Sponsors Diabetes Canada.

Introduction

You are being asked to participate in a research study designed to examine the effect of oral administration of freeze-dried Saskatoon berry on glucose metabolism, insulin resistance, and gut microbiota in a healthy population. Before you decide to participate, it is important to carefully read through this consent form and understand what it says. Make sure all your questions are answered and take the time you need to make a decision. If you decide to participate, you will be asked to sign this consent form. The study doctor and institution are receiving funds from the sponsor, Diabetes Canada, to conduct this study.

Why is this study being done?

Recent research results suggest that Saskatoon berry can reduce high fat-high sugar diet-induced metabolic disorders and vascular inflammation in mice with type 2 diabetes. The beneficial effects of Saskatoon berry may have an impact on gut microbiota to generate

the above-mentioned results. The effects of Saskatoon berry on glucose metabolism, insulin resistance, and gut microbiota in humans remain unknown.

How is the study designed? What is expected of me?

Healthy subjects (males and females, 18-75 years of age) in Winnipeg, who voluntarily signs an informed consent approved by the Research Ethics Board at the University of Manitoba, will be eligible for the study. Exclusion criteria include: 1) candidates have a history of myocardial infarction, stroke, hypertension, diabetes, hyperlipidemia, chronic kidney disease; 2) participants are taking hypoglycemic, anti-hypertensive, lipid-lowering medications or antibiotics.

Dietary product: Freeze-dried Saskatoon berry has been obtained from Prairie Berries Inc. The berries were freshly frozen, and no supplementation was added to the dried berry. The product has been processed by certified facilities and the batch of dried berry has passed pathogen analysis. You will be asked to eat 40 g/day of freeze-dried Saskatoon berry during breakfast for 10 weeks.

Scheduled visits:

Visit 1: Our research coordinator will meet with you to review the study and obtain consent if you are interested in participating. We will ask you to complete a questionnaire about your dietary intake and physical activity. Measurements of body weight, height, and blood pressure will be taken during the visit. This could be done at a place that is convenient for you. A stool sample collection kit and instruction for collection will be provided to you at this visit. Please collect a stool sample with the collection kit within 1 week before Visit 2.

Visit 2 (<1 week from visit 1 and before the start of berry administration): Please bring the stool sample to us at this visit. You will be asked to fast overnight and do a 75g oral glucose tolerance test (OGTT) at the Health Science Centre Lab. To take the OGTT test, you drink about 8 ounces of water with 75g glucose mixed in. Insulin, lipid profile and inflammation markers (C-reactive protein, TNFα, PAI-1, this blood test shows if there are inflammations in the body) will be drawn while fasting. The total amount of blood samples at this visit is 15 ml (3 tablespoons). You will receive a package of dried Saskatoon berry (for 5 weeks supply) and instruction from the administration.

Visit 3 (at 5 weeks after the start of administration of Saskatoon berry): We will ask for your feedback regarding the intake of Saskatoon berry. We will take your body weight, blood pressure, and heart rate at this time. A stool sample collection kit and instruction for collection will be provided to you at this visit. This could be done at a place that is convenient for you.

Visit 4 (at 10 weeks after the start of the dietary regimen):

You will be asked to repeat the OGTT and other tests as you did at the beginning of the study. You will be asked to collect a stool sample with the collection kit within 1 week before your lab test. Your body weight, blood pressure, and heart rate will be taken. Questionnaires on dietary intake, physical activity, and feedback about the study will be completed.

How long will I be involved in the study?

Your participation in the study will last for 10 weeks.

What are the potential risks I may experience?

There are no major risks associated with participating in this study. However, you might not like the taste of the Saskatoon berry. Drawing blood may result in pain, bruising, bleeding, or irritation at the site of the needle stick. There is also a slight possibility of fainting or infection.

Can I expect to benefit from participating in this research study?

There may or may not be a direct medical benefit to you from participating in the study. You are helping scientists to understand more about the effects of Saskatoon berry and its effects on improving health.

Do I have to participate? What alternatives do I have?

You can choose not to participate in this study. Your participation in this study is strictly voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving.

If I agree now, can I change my mind and withdraw later?

You may withdraw from the study at any time without any impact on your current or future care at the site. If you decide to withdraw your consent, the study team will no longer collect your information for research purposes, and you will no longer be expected to participate in the study sessions. Any information collected before you withdrawing from this study will be destroyed unless you provide permission for us to still use it.

Will I be paid for my participation or will there be any additional costs to me?

You will receive a $50 gift card at the end of the study. You will not receive any monetary compensation for your participation. There are no associated costs to you for participating in this study.

How is my personal information being protected?

As a participant, you will be provided with a unique study ID which does not involve any information or identifiers that could identify you. This coded identifier will be used with all data collection documentation specific to the research trials and allow participants to remain confidential to anyone indirectly viewing this information.

Any collected samples will be coded as the order of recruitment but not personal identification information. The codes will appear on any samples including those submitted to other institutes for service analysis.

As well, only research staff directly involved in this research will have access to the information collected. All data collected will be kept on computer systems specific to the research project and that requires a password to log in. It is expected that the research site will follow policies and guidelines to protect participants' information. The research site will secure all participant consent forms that are protected in a locked cabinet/office in a location the lead researcher has access to.

Some study data or biological samples and information from the study may be sent outside of the University of Manitoba to other researchers, academic institutions, health care facilities, or organizations for further analysis, testing, or as part of the research study.

Information gathered in this research study may be published or presented in a public forum, however, your name and other identifying personal information will not be revealed. Increasingly, the scientific community, the granting agencies, and medical scientific journals require that data be stored and made available for secondary review and analysis. For publication purposes, your de-identified study data may be shared with other researchers from other institutions for secondary analysis or other research purposes. Any information or biological samples sent out of the University of Manitoba will not show your name and address, or any other identifiable personal information about you. However, despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed.

Any publications and/or reports produced from these trials will not include any identifying information of the participants or their infants. Research records will be kept for 10 years. At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

Organizations that may inspect and/or copy your coded research results for quality assurance and data analysis include The University of Manitoba Health Research Ethics Board, who approved this study.

Do the investigators have any conflicts of interest?

The investigators have no conflicts of interest to declare related to this study.

Your rights

Your decision to participate in this study or not will not affect your treatment in any way. In particular, participating in this study will not in any way prevent you from receiving the routine care from the clinic from where you were referred. If you decide to participate, you are free to withdraw your consent and stop your participation at any time. If you have any questions, now or later, we will be happy to answer them. You do not give up any legal rights by signing this form.

How Can I Get More Information?

To receive additional information about the research study from the Principal Investigator, contact Dr. Garry Shen at 204-780-3816, or from the Research Coordinator, contact Amy Hui at 204-789-3985.

For questions about your **rights as a research subject**, you may contact:
The University of Manitoba, Bannatyne Campus Research Ethics Board Office at 204-789-3389.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this study with a member of the research study team. I have had my questions answered by them in a language I understand.

The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any research study team member to participate in the research by any statements or implied statements. Any relationship I may have with the research study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time.

I understand that information regarding my identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes. By signing this consent form, I am not waiving any legal rights. I freely agree to participate in this project: **Protocol for a pilot study on the effects of Saskatoon berry on glucose metabolism, insulin resistance, and gut microbiota in healthy human subjects.**

Participant's Signature: _____Date: _____

Printed Name: _____

I have explained the research to the participant and, to the best of my knowledge, the participant has understood the proposed research and freely consented to research participation.

Delegate Signature:_____Date: -
_____

Printed Name: _____