Title of Research Study: *A pilot study of activated charcoal in healthy volunteers*

Investigator Team Contact Information: *Armin Rashidi MD, PhD*
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Armin Rashidi MD, PhD
Investigator Departmental Affiliation: Division of Hematology, Oncology and Transplantation
Phone Number: 612-625-9604
Email Address: arashidi@umn.edu

Supported By: This research is supported by The Clinical and Translational Science Institute (CTSI) Research Services Pilot Award.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being asked to take part in this research study?

You have answered an advertisement to take part in a study on activated charcoal. You have been invited to take part as a healthy volunteer because you have not had any stomach or intestinal diseases in the past month, are not currently taking medications and are not planning to undergo an endoscopy while you are on this study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Activated charcoal “AC” has long been used as an antidote for poisoning. AC is an odorless and tasteless substance that works by trapping toxins in the gut, preventing their absorption.

This study is primarily a “taste test,” focusing on the palatability and safety of different formulations of AC solution. Once these solutions have been tested in healthy volunteers, like

yourself, we plan to do another study to test AC solutions in patients.

How long will the research last?
We expect that you will be in this research study for about two weeks – this will consist of 6 days (Monday, Tuesday and Wednesday for 2 weeks) of clinic visits followed by 4 short daily (Thursday and Friday for 2 weeks) phone calls with a study team member.

What will I need to do to participate?
You will be asked to visit the research unit for six days, drink a 4 oz (half a cup) AC solution, then rate your experience. You will also be asked to be available for four short telephone calls to discuss your experience and whether or not you have had any side effects.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?
The physical risks of this study are low. The most likely risk of AC is constipation or bloating. The most severe, albeit uncommon, risk of AC is aspiration (accidentally sucking the fluid into your lungs).

There is a small risk of loss of confidentiality; however steps will be taken to minimize this by assigning each subject a unique identifier at the time of study enrollment.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?
There will be no direct benefit to you for study participation.

What happens if I do not want to be in this research?
There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study
The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 12 people here will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?
There are no special evaluations for this study and participating in this study will not affect your relationship with the University of Minnesota Medical Center. You will be asked to:

Physical Exam: A physical exam will be conducted before and during the study. The exam will include measurements of weight, height, temperature, blood pressure, heart rate and respiratory rate.

Drink an AC Solution: Every Monday, Tuesday and Wednesday for two weeks, you will be asked to visit the research unit, where you will be given a 4 oz solution consisting of an amount of AC mixed with either tap water or apple juice. The amount of AC and the mix-in liquid will change every 3 days. The dose combinations you drink will depend on a computerized assignment designed to test each possible combination with six different volunteers.

After drinking the AC solution, you will be asked to stay in the research unit for fifteen minutes.

Rate Your Experience: You will be given a 1 page rating sheet and asked to rate the product.

Telephone Call: On Thursday and Friday each week of your participation, a member of the study team will call you and ask if you have had any issues that may be related to drinking the solution.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time. You can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, contact the investigator or tell a study team member. We may want to ask you whether the study product experience is related to you wanting to leave the study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

When AC is used to treat poisoning, it can cause nausea or vomiting. However, the amount of AC used in this study much smaller than what is used to treat poisoning. The amount of AC given in this study may cause constipation, bloating, or make your stools (poop) look dark or tarry.

Additionally, it is possible that you may aspirate (inhale, cough or vomit) the AC into your lungs. Aspirated AC can cause lung complications including inflammation and trouble breathing.

AC may decrease the effectiveness of other medications if used at the same time.

<u>Risks associated with breach of confidentiality:</u>

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure

confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on the product rating forms. A separate list will be maintained that will links each participant's name to the study identification number for future reference and communication.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. You should not be or become pregnant while on this research study. If you are a sexually active woman, you should use an effective means of birth control while participating in this research study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

- The University of Minnesota, and the study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the University of Minnesota workforce who provides services in connection with this study.
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA), the U.S. Department of Health & Human Services (DHHS), and the Office for Human Research Protections (OHRP)).
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as the University of Minnesota IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The Masonic Cancer Center at the University of Minnesota and/or their designee

If you decide to participate in this study, some private health information about you will be stored in a computer database at the University of Minnesota Masonic Cancer Center. This information will include your name and study number, date of birth, race/ethnicity, and information about your participation in this study. The purpose of storing this information is to assist the Cancer Center in creating reports about research and in making sure that research studies are being done correctly. Your information will not be used for any other purpose. There are no plans to erase information from the database. It will be stored indefinitely at the Masonic Cancer Center.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including

first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you a 50 dollar Amazon gift card for your time and effort. You will receive the gift card after completing the study.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Signature Block for Witness:

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process