Title: Does a soft drink mixture improve tolerance of activated charcoal in an adult without affecting efficacy: A randomized controlled crossover study

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RESEARCH SUBJECT CONSENT & AUTHORIZATION FORM

Title:	Does a soft drink mixture improve tolerance of activated charcoal in an adult without affecting efficacy: A randomized controlled crossover study
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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should you know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will you be in this research?

We expect that your taking part in this research will last _10__ hours

Why is this research being done?

The purpose of this research is to determine if a soft drink and activated charcoal mixture adequately reduces systemic absorption in healthy adults who have taken a supratherapeutic dose of acetaminophen in addition to improving its tolerance.

What happens to you if you agree to take part in this research?

If you decide to take part in this research study, the general procedures include ingesting a pre-determined amount of acetaminophen (Tylenol), followed by activated charcoal. After that, blood work will be obtained to check the acetaminophen levels in your blood. This will take approximately 5 hours. You will then return to repeat the study, allowing us to compare charcoal by itself with charcoal mixed with a soft drink.

Could being in this research hurt you?

The most important risks or discomforts that you may expect from taking part in this research include pain from IV insertion, nausea or discomfort from the taste of the charcoal. It is important to note that as part of the study, you will be taking more acetaminophen than you would typically ingest. The amount you will take is well below the toxic dose. We have extra safeguards in place to ensure no one receives a toxic dose of acetaminophen.

Will being in this research benefit you?

It is not expected that you will personally benefit from this research

Possible benefits to others include improved management of poisoned patients in the future by providing a more palatable vehicle for charcoal administration, which can reduce the amount of poison they are exposed to.

What else should you know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is that you will need to abstain from alcohol the day before, day of, and day after the study. You will also be asked to avoid acetaminophen for 5 days before, day of, and 5 days after the study.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

Why is this research being done?

To determine if a soft drink and activated charcoal mixture adequately reduces systemic absorption in healthy adults who have taken a supratherapeutic dose of acetaminophen in addition to improving its tolerance.

About 5 subjects will take part in this research.

What happens to you if you agree to take part in this research?

PROCEDURES

If you volunteer to participate in this study, you will be asked to come in for three different visits.

Visit 1 (today)

Here, we will obtain a consent form and a screening form to determine eligibility for the study.

Visit 2

Please arrive by 8AM after an overnight fast to have commenced at 4 am. Your age will be recorded and your height and weight will be measured in order to calculate your BMI.

Following this, you will be fed a light breakfast of 2 pieces of dry toast and 200 mL of water. A peripheral IV will be placed in the antecubital fossa for blood drawing. The area will be cleaned with an alcohol wipe and a tourniquet will be placed on the arm proximal to planned IV insertion site.

One hour after breakfast, you will be given 50mg/kg of acetaminophen (Tylenol) along with 150 mL of water in the form of 325 mg tablets. The purpose of doing this is to more closely mimic the overdose setting.

One hour after the acetaminophen consumption, you will be given the charcoal mixture. You will be given either 50 g of Actidose-aqua, a pre-mixed charcoal-water slurry, **OR** 50 g of Actidose-aqua in addition to 240 mL of a soft drink. You will be asked to rate the appearance, smell, flavor, texture, ability to swallow, and overall appeal of the charcoal mixture on a scale of 1-10, with 1 being the worse and 10 being the best.

We will draw your blood ten times in a gold or mint tube after ingestion of the charcoal mixture. The first will be at time 0 (time of consumption of the mixture). The next will be at 15, 30, 45, 60, 75, 90, 120, 180, 240 minutes. These samples will be taken to the lab for processing.

You will receive a light snack of crackers and water no sooner than 3 hours after the charcoal was consumed (4 hours after ingestion of the acetaminophen).

Visit 3

Please arrive by 8AM after an overnight fast to have commenced at midnight the night prior. Your age will be recorded and your height and weight will be measured in order to calculate your BMI.

Following this, you will be fed a light breakfast of 2 pieces of dry toast and 200 mL of water. A peripheral IV will be placed in the antecubital fossa for blood drawing. The area will be cleaned with an alcohol wipe and a tourniquet will be placed on the arm proximal to planned IV insertion site.

One hour after breakfast, you will be given 50mg/kg of acetaminophen (Tylenol) along with 150 mL of water in the form of 325 mg tablets. The purpose of doing this is to more closely mimic the overdose setting.

One hour after the acetaminophen consumption, you will be given the charcoal mixture. You will be given the other mixture that you did not receive during Visit 2, that is, either 50 g of Actidose-aqua, a pre-mixed charcoal-water slurry, **OR** 50 g of Actidose-aqua in addition to 240 mL of a soft drink. You will be asked to rate the appearance, smell, flavor, texture, ability to swallow, and overall appeal of the charcoal mixture on a scale of 1-5, with 1 being the worse and 5 being the best.

We will draw your blood ten times in a gold or mint tube after ingestion of the charcoal mixture. The first will be at time 0 (time of consumption of the mixture). The next will be at 15, 30, 45, 60, 75, 90, 120, 180, 240 minutes. These samples will be taken to the lab for processing.

You will receive a light snack of crackers and water no sooner than 3 hours after the charcoal was consumed (4 hours after ingestion of the acetaminophen).

What are your responsibilities if you take part in this research?

If you take part in this research, you will be responsible to:

- Avoid alcohol the day before, day of, and day after the study
- Avoid acetaminophen for 5 days before, day of, and 5 days after

Could being in this research hurt you?

You may experience some discomfort with IV insertion. You may experience nausea or vomiting with the charcoal administration.

Acetaminophen in overdose can lead to liver injury. However, the amount you will be ingesting (40 mg/kg) is well below the toxic dose of 150 mg/kg. In addition, weight cutoffs in place will not allow any participant to receive more than 4g of acetaminophen, the recommended max daily dose. The weight cutoffs are such that even if the patient who weights the least accidently received the dose intended for the smallest person, it would still not exceed 150 mg/kg (max weight allowed 3X the weight of the smallest participant). Finally, as an added level of security, a 4-hour acetaminophen level will be drawn, which will be used to ensure that your acetaminophen level is not toxic. If, for some reason, it was toxic (which would only occur if there was a dosing error), there is an antidote which is essentially nearly 100% effective if given within 8 hours.

In addition to these risks, taking part in this research may harm you in unknown ways.

Will it cost you money to take part in this research?

No, outside of transportation/parking costs

Will being in this research benefit you?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include improvement in the care of poisoned patients.

What other choices do you have besides taking part in this research?

Your alternative is to not take part in the research.

What happens to the information or specimens collected for this research?

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Who can answer your questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (315) 464-4317 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if you are injured because of taking part in this research?

In the event of a research related injury, treatment is available at University Hospital but is not free of charge. The costs will be billed to you or your insurance company in the usual fashion. SUNY Upstate Medical University has no funds set aside to compensate you for injuries. You have not waived any of your legal rights by signing this form.

Can you be removed from this research without your approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- You are unable to take the research medication
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if you agree to be in this research, but you change your mind later?

If you decide to leave this research, contact the research team so that the investigator can be removed from the study. There are no risks to leaving early

Will you be paid for taking part in this research?

For taking part in this research, if you complete all parts of the study, you will be paid $150. Your compensation will be broken down as follows:

- Participants will receive a Visa gift card within 14 days of the final study day
- If participants do not complete the entire study, they will not receive compensation

By accepting payment for participating in this study, identifying information about you (such as your full name and social security number) needs to be collected and may be shared with auditors and the finance office to ensure compliance with Internal Revenue Service (IRS) requirements. If you do not want to provide this information for payment reasons, you have the option to decline the payment and still participate in the study. Please note that if you earn $600 or over in a calendar year as a research subject, you may have to pay taxes on these earnings. Information provided for payment purposes will be kept confidential.

Confidentiality of records and authorization to use/share protected health information for research:

If you agree to participate in this research, identifiable health information about you will be used and shared with others involved in this research. For you to be in this research we need your permission to collect and share this information. Federal law protects your right to privacy concerning this information.

When you sign this consent form at the end, it means that you have read this section and authorize the use and/or sharing of your protected health information as explained below. Your signature also means you have received a copy of Upstate's Notice of Privacy Practices.

Individually identifiable health information under the federal privacy law is considered to be any information from your medical record, or obtained from this study, that can be associated with you, and relates to your past, present, or future physical or mental health or condition. This is referred to as protected health information.

Your protected health information will be kept confidential. Your identity will not be revealed in any publication or presentation of the results of this research.

Why is it necessary to use/share your protected health information with others?
The main reason to use and share your health information is to conduct the research as described in this consent form. Your information may also be shared with people and organizations that make sure the research is being done correctly, and to report unexpected or bad side effects you may have.

In addition, we may be required by law to release protected health information about you; for example, if a judge requires such release in a lawsuit, or if you tell us of your intent to harm yourself or others.

What protected health information about you will be used or shared with others as part of this research?
We may use and share the results of tests, questionnaires, and interviews. We may also use and share information from your medical and research records. We will only collect information that is needed for the research.

Who will be authorized to use and/or share your protected health information?
The researchers, their staff and the staff of Upstate Medical University participating in the research will use your protected health information for this research study. In addition, the Upstate Institutional Review Board (IRB), a committee responsible for protecting the rights of research subjects, and other Upstate Medical University or University Hospital staff who supervise the way the research is done may have access to your protected health information.

The researchers and their staff will determine if your protected health information will be used or shared with others outside of Upstate Medical University for purposes directly related to the conduct of the research.

With whom would the protected health information be shared?

Your protected health information will not be shared

All reasonable efforts will be used to protect the confidentiality of your protected health information. However, not all individuals or groups have to comply with the Federal privacy law. Therefore, once your protected health information is disclosed (leaves Upstate Medical University), the Federal privacy law may not protect it.

For how long will your protected health information be used or shared with others?
There is no scheduled date at which this information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

Can you withdraw your authorization to collect/use/share your protected health information?
You always have the right to withdraw your permission (revoke authorization) for us to use and share your health information, by putting your request in writing to the investigator in charge of the study. This means that no further private health information will be collected. Once authorization is revoked, you may no longer participate in this research activity, but standard medical care and any other benefits to which you are entitled will not be affected. Revoking your authorization only affects uses and sharing of information obtained after your written request has been received, but not information obtained prior to that time.

Even after you withdraw your permission, Upstate Medical University may continue to use and share information needed for the integrity of the study; for example, information about an unexpected or bad side effect you experienced related to the study.

Can you have access to your health information?
At the end of the study, you have the right to see and copy health information about you in accordance with the SUNY Upstate Medical University policies; however, your access may be limited while the study is in progress.

Statement of Consent to Participate in Research & Authorization to use and share personal health information

- Participation in this study is entirely voluntary. You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- I have read this information and this study has been explained to me.
- It has been written in a language that I understand.
- All my questions about the study have been answered to my satisfaction.

For Subjects 18 Years Of Age And Older

I hereby give my consent to participate in this research study and agree that my personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

_____ _____
Signature of subject Date

_____ _____
Signature of Person Obtaining Consent/Authorization Date

_____
Name of Person Obtaining Consent/Authorization