Key Information for:
Coronavirus Induced Acute Kidney Injury: Prevention using Urine Alkalinization

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done and what is involved?

The Coronavirus (COVID-19) is impacting the entire world. Since this virus is new, there is not a lot of information available for doctors and clinical staff on how the disease behaves, how to treat patients, and the outcomes of patients. COVID-19 is known to affect kidney function and cause Acute Kidney Injury (AKI). The objective of this study is to determine the role of urine alkalization in the prevention of the development and progression of AKI in critically ill patients with COVID-19. Urine alkalization is a process that helps to lower high levels of acid in the blood or urine that can be caused by certain medicines or conditions. It has been used for a long time in treatment of various drug toxicities. This study hopes to better understand how COVID-19 impacts the patient's kidneys.

Should you choose to participate, you will be randomized to one of the two groups - standard of care (control) group or the study (intervention) group. If you are randomized to the study group you will be given an intravenous medication called sodium bicarbonate to alkalize your urine. If you are randomized to the standard of care group, you will receive routine treatment and will be asked to provide urine samples as part of the study during your hospital stay. If you are randomized to the study group you will be given the medication intravenously and you will be asked to provide blood specimens to monitor your condition, and urine samples as part of the study during your hospital stay. We will be collecting some pertinent information from your medical record both during and from before your hospital stay. The blood and urine sample collections will happen during your hospital stay.

Do I have to participate and what are the risks involved?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with the study doctor or refer to the "Alternatives" section in the consent form. You may not directly benefit from participating in this research.

Risks from participation in this study are minimal and may include some pain and a small risk of bleeding, bruising, or infection at the puncture site for the blood draws. There is also a small risk of fainting. These risks will be minimized by making every attempt to collect your blood samples from existing catheters in one of your veins or arteries to reduce the need for additional needle punctures if possible. We will make every attempt to coordinate our blood draw at the time you are to receive your blood draw for your standard of care treatment. However, there may be situations when we may have to get a separate blood draw. Sodium bicarbonate has been used in different treatment protocols for many years so its risks are generally well known. It is usually well tolerated but people may develop metabolic alkalosis (high base level in body), low calcium levels or hypervolemia (high fluid level in body). Alkalization of urine with sodium bicarbonate can also increase the elimination of certain drugs including hydroxychloroquine. You will be carefully monitored for these adverse effects during the study period. Though there is a lot of experience with sodium bicarbonate, there is always a risk of uncommon or previously unknown side effect(s) or event.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Dr. Ankit Sakhuja at 304-598-6092 from the Division of Cardiovascular Critical Care, Department of Cardiovascular and Thoracic Surgery at WVU Medicine.

For more information, please see the Informed Consent Form.

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Informed Consent for Research | More than Minimal Risk

Principal Investigator (PI) |	Ankit Sakhuja, MD
Department |	Division of Cardiovascular Critical Care, Department of Cardiovascular and Thoracic Surgery
Sponsor or Funding Source |	WVCTSI
WVU IRB Protocol # |	2005006707
Study Title |	Coronavirus Induced Acute Kidney Injury: Prevention using Urine Alkalinization

Introduction

You,_____, have been asked to participate in this research study which involves determining the feasibility and safety of a treatment protocol of acute kidney injury in patients with COVID-19 who are hospitalized, which has been explained to you by_____. This study is being conducted by Ankit Sakhuja, MD in the Department of HVI Critical Care Medicine at West Virginia University.

Purpose

The purpose of this study is to better understand how COVID-19 impacts patients' kidneys. Since this virus is new, there is not a lot of information available for doctors and clinical staff on how the disease behaves, how to treat patients, and the outcomes of patients. COVID-19 is known to affect kidney function and cause AKI. Preventing AKI early on in COVID-19 patients may help reduce the overall burden and complications of AKI as the COVID-19 disease progresses.

The main objective of this study is to determine the role of urine alkalization in prevention of the development and progression of AKI in critically ill patients with COVID-19. Urine alkalization is a process that helps to lower high levels of acid in the blood or urine that can be caused by certain medicines or conditions. This study hopes to better understand how COVID-19 impacts the patient's kidneys.

Medical information as well as biospecimens (blood and urine samples) from patients who test positive for COVID-19 can provide important information to doctors and clinical staff on better ways to treat patients. This study will randomly assign you to either the standard of care (control) or study (intervention) group. If you are randomized to the study group you will be given an intravenous medication called sodium bicarbonate to alkalize your urine. If you are randomized to the standard of care group, you will receive routine treatment and will be asked to provide urine samples as part of the study during your hospital stay. If you are randomized to the study group you will be given the medication intravenously and you will be asked to provide blood specimens to monitor your condition, and urine samples as part of the study during your hospital stay. We will be collecting some pertinent information from your medical record both during and from before your hospital stay. The blood and urine sample collections will happen during your hospital stay. We are planning to enroll approximately 40 patients at WVUMedicine.

Description of Procedures

This study involves assigning you to one of two groups and collecting blood and urine samples during your hospitalization.

If you agree to be a part of this study, you will have the procedures described below:

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- Review of medical history: You agree to allow the study staff to review your medical records to learn more about your general medical history including any illnesses you have, prior treatments, prior testing, procedures, etc.
- Review of medications: You agree to allow the study staff to review your medical records to learn about medications that you are have taken in the past, are currently taking at the start, and throughout thestudy.
- Physical exam and vital signs: You agree to allow the study staff to review your medical records to learn about information from your physical examinations prior to and during your hospital stay, including height, weight, temperature, blood pressure, and pulse.
- If you are randomized to the control group, your care will be managed according to routine procedures. The only part of your participation that will be extra will be a collection of urine. We will collect urine from an existing catheter up to 3 times throughout your hospital stay. This urine would normally be disposed of, so there is nothing additional we need to do to you to collect this specimen.
- If randomized to the study group the following will be done: urine alkalinization medication will be initiated and continued for 10 days or until you are discharged from the ICU or step-down unit, develop stage 3 AKI, or the safety end point of maintaining your fluid balance is reached.
    - There are tests necessary to monitor your condition. Many of these tests are already performed as part of your routine care. We will use as many of the test we can from your routine care. This study will simply ensure that these measurements are timed to maximize your safety. If for any reason you would not have the necessary tests as part of your routine care, we would need to draw blood and urine to perform them.
        - Blood Collection: Some of these blood samples will be collected every 12 hours and some every 24 hours. If they are not already done as part of your routine care, the most we would draw would be two (2) blood draws every day for up to ten (10) days. One blood draw would be about 2mL (about 2/3 of a teaspoon) and the other one about 1.5mL (about 1/3 of a teaspoon). The total amount of blood that could be drawn for the entire study is about 60mL (about 12 teaspoons). The least you could have drawn is zero (0). Again, many of these are drawn for your routine care.
            - Blood will be collected to perform tests specifically related to your acid-base status, kidney functioning and electrolyte levels. If needed for the study, blood will be collected at multiple times from an existing catheter (tube) in one of your veins or arteries if possible to reduce the need for additional needles. If it is not possible to collect blood from an existing catheter (tube), then blood will be drawn by a routine needle puncture of a vein (usually in the arm). We will make every effort possible to do this at the time you get your routine care labs collected to limit the number of times you get a needle puncture. You will be monitored by study personnel after blood collection to see if you are experiencing any unwanted side effects.
                - Urine Collection: Urine will be collected every 2-4 hours until the target pH is reached and then every 6-8 hours to ensure urine pH is in the appropriate range for urine alkalinization (≥7.2). Your urine is routinely discarded, so we will collect it before being discarded.
- For both groups of patients, we will be storing some of your urine samples for future research. This urine would be routinely disposed of. We are also asking for your permission to store some of your health information with your samples so that your samples will be more useful for research. We plan to continue to review your medical record to update your health information.

Risks and Discomforts

Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting. These risks will be minimized by collecting your blood samples from existing catheters in one of your veins or arteries to reduce the need for additional needle punctures if possible. If not

possible, we make every attempt to coordinate our blood draw at the time you are to receive your blood draw for your standard of care treatment.

Sodium bicarbonate has been used in different treatment protocols for many years so its risks are generally well known. It is usually well tolerated but people may develop metabolic alkalosis (high base level in body), low calcium levels or hypervolemia (high fluid level in body). Alkalization of urine with sodium bicarbonate can also increase the elimination of certain drugs including hydroxychloroquine. You will be carefully monitored for these adverse effects during the study period. Though there is a lot of experience with sodium bicarbonate, there is always a risk of uncommon or previously unknown side effect(s) or event.

The risk from allowing your samples and health information to be stored is the potential loss of privacy; however, we will make every effort to protect your privacy by labeling your samples and information only with a code and keeping the key to the code unavailable to other researchers.

In addition, there is always the risk of uncommon or previously unknown side effect(s) or event.

Alternatives

You do not have to participate in this study.

Benefits

You may not directly benefit from participating in this research. The knowledge gained from this study may help us understand, prevent, treat, or cure the illnesses and conditions studied. The knowledge gained from this study may eventually benefit others.

Financial Considerations

If you are in the study group, the study sponsor, WVCTSI, will pay for the costs of the sodium bicarbonate and the lab tests associated with managing your care while on the medication, that would not be part of current therapy for your disease or condition. If you are in the control group, your routine care will be billed to you or your insurance.

Volunteering to participate in this study will be at no extra cost to you nor will you be compensated for participating.

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the Internal Revenue Service (IRS).

Your data, health information, research results, specimens, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights nor will you share in any money or commercial profit that the investigators, West Virginia University, or their agents may realize.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

Identifiers will be removed from the identifiable private information and the identifiable biospecimens and after that removal information or biospecimens by be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

This research is not planning to include whole genome sequencing.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals/WVU Medicine/WVUHS

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site's research and medicalstaff.
- Health care providers who provide services to you as part of this researchstudy.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- WVCTSI and the people that they use to oversee, manage, or conduct the research.
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.
- WVU Heart and Vascular Institute (HVI) and our partner institutions involved in the study.

The Following Information Will Be Used

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Information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans, and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as reviewing the safety or effectiveness of the study drug, developing a better understanding of COVID-19, and improving the design of future studies.

You may Cancel this Authorization at Any Time by Writing to the Principal Investigator

Ankit Sakhuja, MD
1 Medical Center Drive, Box 8003
Morgantown, WV 26506

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until we have completed all work related to the study. At that time, you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Compensation

There is no money set aside to help treat you if you get hurt or sick in this study. The study doctor and WVU or its partners do not have special funds to pay for research related injuries if they occur.

If you are injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Ankit Sakhuja at 304-598-6092 if you are injured or for further information.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. If you choose to withdraw your participation from the study, the data and biospecimens collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal.

Refusal to participate or withdraw will not affect your future care or status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

Incidental Findings

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Generally, tests done for research purposes are not meant to provide clinical information. If it is determined that information generated from this research is clinically relevant to you individually, the Principal Investigator, Dr. Ankit Sakhuja, or his delegated staff will contact you.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Dr. Ankit Sakhuja at 304-598-6092. You can also contact Study Personnel at 304-598-6092.

If you are hurt from being in this research, you should contact Dr. Ankit Sakhuja at 304-598-6092. If injury occurs outside of business hours and is related to your participation in this research, please contact Dr. Ankit Sakhuja at 304-598-4478

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protection (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Future Contact

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section.

- ☐ Yes, I want to be contacted if future research studies, for which I am qualified, become available.
- ☐ No, I **do not** want to be contacted if future research studies, for which I am qualified.

Signatures and Authorization

You have been given the opportunity to ask questions about the research (if applicable) and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to participate in this research.

Signature of Subject or Subject's Legal Representative

Printed Name Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name Date

Impartial Witness Signature (if applicable)

The participant or legal representative has had the opportunity to have questions addressed. As the impartial witness, I confirm that the participant willingly agrees to be in the study.

Signature of Impartial Witness

Printed Name Date

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