Study Title:	Randomized Trial of Empiric Versus Selective Prevention Strategies for Kidney Stone Disease
Version Date:	February 7, 2022
PI:	Ryan Hsi, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:
You are being asked to take part in this research study because kidney stones can recur in the future. Currently, 24-hour urine testing is standard practice to help clinicians and patients determine how to prevent future kidney stones. However, whether diet and medications prescribed based on 24-hour urine testing is helpful is not well understood.

During the course of the 2-month study, you will have three 24-hour urine tests done. You will be prescribed diet and medication interventions to prevent kidney stones. You will be assigned either to an empiric arm – that is, a group that will have standard diet and medications; or to a selective arm – that is, a group that will have adjusted diet and medications based on 24-hour urine testing.

There are risks to the study. We do not expect major risks from diet recommendations alone. There is a risk of side effects from the medications. The most common side effects are stomach upset, nausea, diarrhea. Less common are dizziness, lightheadedness, fatigue, muscle cramps. Rarely they can cause abnormal blood potassium, arrhythmias (abnormal heart beat), and rash. We will closely monitor you for these including regular heart rate, blood pressure, and blood potassium checks. All of the medications in this study are standard, commonly used medications for kidney stone prevention for many years.

There may be benefits to you. At the end of your study participation, we will be able to share with you the results of your urine testing. You may notice a decrease in how frequently your kidney stones form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information. Approximately 56 participants will be enrolled at Vanderbilt University Medical Center (VUMC).

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Side effects and risks that you can expect if you take part in this study:

Common ≥10% – (any medication) stomach upset, nausea, diarrhea, constipation, frequent urination (fluid intake)

Less common <10% – dizziness, lightheadedness, fatigue, muscle cramps (any medication)

Rare (≤1%) – abnormal blood potassium (indapamide), arrhythmia (potassium chloride and potassium citrate), rash (any medication)

Risks that are not known:

Because this treatment is investigational, there may be risks that we do not know about at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: An improved understanding of

- How 24-hour urine testing impacts urinary parameters to reduce kidney stone recurrence
- How diet and medications change urinary parameters
- Side effects of diet and medication interventions to prevent kidney stones

Procedures to be followed:

1. At the initial study visit, you will have your blood pressure, heart rate, and weight measured. You will also have blood drawn for some basic laboratory values, if these labs have not been done recently. You will complete 24-hour urine testing at home, if you have not done one recently. You will be provided the collection kit and a set of instructions. The kit will be mailed to a laboratory.
2. You will be assigned to an intervention to prevent kidney stones. The intervention will include dietary recommendations and may include medications.
    a. The dietary recommendations may include
        i. Increase water intake of at least 2 liters daily
        ii. Reduce soda intake to less than 3 cans per week
        iii. Restrict animal proteins
        iv. Increase vegetable and fiber intake
        v. Increasing fruit and vegetable intake
        vi. Reduce salt intake for goal <2000mg sodium daily
3. After 1 month, you will have your blood pressure, heart rate, and weight measured. You may have blood collected. You will complete a second 24-hour urine testing at home. You will be provided the collection kit and a set of instructions. The kit will be mailed to a laboratory.

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4. Your intervention will be adjusted to better prevent kidney stones. The intervention will include dietary recommendations and may include medications.
5. After 1 month (the 2nd month), you will have your blood pressure, heart rate, and weight measured. You may have blood collected. You will complete a third 24-hour urine testing at home. You will be provided the collection kit and a set of instructions. The kit will be mailed to a laboratory.
6. When you complete a 24 hour urine test, you will complete a survey (written or web based on a secure website) on your food intakes over the 24-48 hour time period.

Payments for your time spent taking part in this study or expenses:
If you complete the study tasks through one month, you will receive $50. If you complete the study tasks through the second month, you will receive an additional $100.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the NIH to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the NIH to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Ryan Hsi, MD at 615-343-2036. If you cannot reach the research staff, please page the study doctor at 615-322-5000.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
If we are missing information about you or you have missed visits.

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What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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

Confidentiality:
Records and data will be stored and maintained in a secure database called REDCap, that is considered the standard for data collection. Future research may occur on the collected data including secondary analyses. All reasonable effort will be made to prevent a breach of confidentiality. Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Hsi and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

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Study Results:
Any sharing of the research will not contain any information that can be linked to you or any other individual. At the end of your study participation, we will be able to share with you the results of your urine testing.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

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What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____