Dietary Approaches to Stop Hypertension (DASH) Diet effects on Serum Uric Acid (SUA) in adults with hyperuricemia and gout

NCT03569020

October 29, 2018

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Dietary Approaches to Stop Hypertension (DASH) Diet effects on Serum Uric Acid (SUA) in adults with hyperuricemia and gout.**

Application No.: **IRB00153409**

Sponsor: **Rheumatology Research Foundation**

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Tel: 410-502-6444
Fax: 410-502-6446

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital, i.e. all Hopkins affiliates.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood and urine. No specimens will be stored after the study is complete.

- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you.

2. Why is this research being done?

This research is being done to see if eating meals high in fruits, vegetables, nuts, beans, and lean meats, similar to the "Dietary Approaches to Stop Hypertension (DASH)" diet can lower uric acid.

Adults with high blood levels of uric acid have a higher chance of developing gout – a painful inflammatory disease of the joints. People with high uric acid often have low levels of key nutrients as a result of eating few fresh fruits and vegetables. Research studies suggest that these nutrients can lower uric acid – a risk factor for gout. In this study, we want to see if providing encouragement to adopt this healthy and nutritious way of eating will lower uric acid.

During half of this study, participants will be provided foods that are consistent with the DASH diet. During the other half participants are asked to eat their normal home diet without any change to what they typically do. Participants will be randomly assigned to (1) the DASH foods followed by their home diet or (2) their home diet followed by the DASH foods. Participants are entered into 1 of these 2 groups at random, like flipping a coin. Each half of the study lasts 4 weeks.

Adults 18 years or older who are diagnosed with gout or hyperuricemia and have a uric acid greater than 7 mg/dl may join.

How many people will be in this study?

A total of 40 people will be recruited for this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

You will come to Johns Hopkins ProHealth Community Research center.

Screening Visit #1:

To determine if you can participate in this research study, we will:

- Review the informed consent form with you
- Carefully review instructions with you

- Ask you questions about your medical history and medications to determine eligibility
- Ask for your contact information in order to contact you during the study
- Ff eligible, collect blood samples (about 8.5 cc or less than 2 teaspoons). You will be asked to not eat or drink anything except water before the blood sample is collected if you have not done so during the first screening visit:
  - We will use the blood samples to measure your kidney function (creatinine), potassium, glucose (sugar), and cholesterol and uric acid.
  - If your uric acid level is above 7 mg/dL you will be move on to screening visit #2 Collect spot (random) urine samples:
  - we will measure the sodium, potassium, uric acid, and pH (acid level) of your urine

Screening Visit #2:

After your first screening visit, you will then come back for the second screening visit where we will:

- Review your medication history
- Carefully review instructions with you ask you questions about your eating and other habits to determine you eating patterns
- Ask questions about your gout diagnosis and its impact on your quality of life
- Measure your blood pressure (sitting and standing) measure your weight, height, grip strength, ability to stand up, balance

Randomization Visit:

If you remain eligible and interested in the study after the second visit, you will be randomly assigned (by chance, like the flip of a coin) to one of two phases, after one month in one phase, you will then be placed into the other phase:

1. Dietitian-Directed Diet (DDD) phase
2. Usual Self-Directed Diet (SDD) phase

During the trial when you are assigned to the Self-Directed Diet (SDD) advice phase, you will receive a brochure containing information about food and gout. You will be asked to eat your own home diet with no change and come in to ProHealth after 4 weeks. Participants will receive up to $25 for completing their SDD study visit.

During the Dietitian-Directed Diet (DDD) phase, you will receive foods delivered by Shoprite or Amazon Fresh store that contain DASH diet foods (see below). A dietitian will help you order these

foods. You will need to pick up foods weekly at the ProHealth Community Research Center. You will also need to be able to pick up and refrigerate these foods as many will be perishable.

During the DDD phase, you will meet with the study coach for one face-to-face visit for 1 hour followed by weekly brief conversations (about 15 minutes) by phone for 4 weeks. During the trial, on a weekly basis, you will purchase $105.00 worth of fruits, vegetables, nuts and beans through the study dietitian. These groceries will be paid for by the study during this phase, and will be delivered to ProHealth by Shop-Rite or Amazon Fresh once a week. There will be calls as needed to arrange delivery/pick up. After 4 weeks, you will be asked to come in to ProHealth for a study visit. Participants will receive up to $25 for completing their DDD study visit.

We will *not* ask you to change any of the medications you are currently taking that have been prescribed by your regular doctor.

During this randomization visit, we will:

- Review your medication history
- Measure your blood pressure (seated and standing)
- Collect your weight measurement
- Ask questions about physical activity

Follow-Up Visits (Week 4 and Week 8)

You will be asked to come to Johns Hopkins ProHealth community research center. During each of the visits, we will:

- Review your medication history
- Carefully review instructions with you
- Review your eating and other habits
- Measure your blood pressure (sitting and standing)
- Measure your weight, ability to stand and walk Collect spot (random) urine samples:
- We will measure the sodium, potassium, uric acid, and pH (acid level) of your urine Collect blood samples:
  - We will collect 8.5 cc (less than 2 teaspoons) of blood. You will be asked to not eat or drink anything except water before the blood sample is collected if you have not done so during the first screening visit.
  - We will measure your kidney function (creatinine), uric acid, glucose (sugar), and cholesterol.

How long will you be in the study?

You will be in this study for 11 weeks: 3 weeks before the study starts, 4 weeks in phase 1, and 4 weeks in phase 2.

Future Contact

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please check box and sign to indicate your choice below:

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

4. What are the risks or discomforts of the study?

Collecting blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

As someone with a history of high blood pressure, there is naturally some concern that your blood pressure could increase in the period of time you are in the study. This is not a result of anything you will experience while in the study, but simply a response to everyday life. We will monitor your blood pressure during your clinic visits. If it should rise to an unacceptable level, we will suggest that you discontinue participation and return to your physician for treatment.

This is a low risk dietary intervention of fruits vegetable, nuts and beans. We perform safety checks using the blood samples to assess hyperkalemia (high blood potassium levels) or hyperglycemia (high blood sugar), conditions that might be related to the intervention.

There are several questionnaires we will ask you to complete. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

There is the risk that information about you may become known to people outside this study.

5. Are there risks related to pregnancy?

You cannot take part in this research study if you are pregnant. This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There are no direct benefits to you from being in this study. Your participation in the study may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

Yes. For 4 weeks during the trial, we will spend approximately $105 per week to purchase food for you from Shoprite or Amazon Fresh for a total of approximately $420.00 worth of groceries.

All participants will receive $25.00 if you complete the randomization visit and $25.00 for each of the 2 follow up visits. Total potential payment for participation in the study is $420.00 worth of food + $75.00 (for study visits) = $495.00.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful to you.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include

information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be redisclosed.

Part of this study (data safety review and data analysis) will be performed at Beth Israel Deaconess Medical Center. This site will adhere to all the same privacy requirements and study protocols approved by the Johns Institutional Review Board (IRB).

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You may be asked to give us a list of other health care providers that you use.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.
By signing this form, you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you? The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Edgar Miller at 410-502-6444. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Edgar Miller at 410-502-6444 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call Dr. Edgar Miller at cell phone number 410-294-6529 after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-3677382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.