UAB IRB
Approved
06-Jan-2021
until
05-Jan-2022

Consent Form

TITLE OF RESEARCH: Colonization of healthy volunteers with *Oxalobacter formigenes* and its effects on urinary oxalate excretion (Oxalobacter Formigenes Colonization and Oxalate Excretion in Calcium Oxalate Kidney Stone Disease.)

IRB PROTOCOL: IRB-131212001

INVESTIGATOR: John Knight, PhD

SPONSOR: National Institutes of Health (NIH)

Purpose of Research

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you do not have the harmless bacterium *Oxalobacter formigenes* (OxF) in your intestines, and do not have a history of kidney stone disease. Your participation is voluntary. Please read this information carefully and feel free to ask questions about anything you don't understand. The purpose of this research study is to assess the efficacy of ingesting a small amount of the harmless bacterium *O. formigenes* in establishing residence in the guts of human subjects and to determine whether this influences the oxalate passed in urine of healthy volunteers.

Explanation of Procedures

We will first need to establish whether you have OxF in your intestines. You will be asked to provide a stool sample using a stool collection kit, and drop off the samples with the Research Co-ordinator to the Urology Research Lab. If your stool does contain OxF you will not be eligible to participate. If you are not colonized with OxF you will be invited to perform the studies described below.

Screening Phase and Bionutrition Interview

You will be notified of your OxF status in approximately 2 weeks and if you are not positive for OxF you will be asked to obtain three 24 hr urine collections while consuming your at-home diet. If your urinary excretions are within the expected range, an appointment will be scheduled with a nutritionist at the UAB Clinical Research Unit (CRU) to determine your caloric requirements and your willingness to consume a diet prepared in the CRU, which will be controlled in their content of nutrients including oxalate and calcium. A fasted blood sample (2 teaspoons) will also be obtained at this appointment to ensure you are in good health. The nutritionist will also measure your height, weight, waist-to-hip ratio, and estimate your body fat mass. If you are willing to consume the controlled diet, you will then be scheduled to return to the CRU to pick up the food.

Moderately High Oxalate Dietary Phase 1 – Not Colonized with OxF

An appointment will be scheduled for you to return to the CRU to pick up meals and liquids that you will be required to consume over 5 days. Some of these foods will need to be stored in either a freezer or refrigerator for the duration of this study. The meals and liquids you will consume in a day will contain a moderately high level of oxalate(250mg), and a low level of calcium(400mg), and all the calories and nutrients you need. It is important that you do not eat any other foods or drink any other liquid, except the water we provide, over this 5-day period. It is recommended that you also refrain from vigorous exercise.

On days 2 through 5 of this dietary phase you will collect 24 hr urine samples (four total) and at least three stool samples. The stool collection kit contains a fecal collection tube and two fecal swabs. You will fill the fecal collection tube to the line indicated on the side of the tube (approximately 5 grams of stool) and also swab the stool sample with both fecal swabs. Drop off the stool samples within 24 hours to the research co-ordinator or in the blue bin oustside of Kaul 842. 24 hour urine samples should be brought in the following day to the CRU or to the study coordinator (for instance, you will return the day 2 24 hour urine on the morning of day 3).
On the morning of the 5th day, you will return to the CRU and provide a fasted blood sample (2 teaspoons) to measure the level of oxalate in your blood. You will then be provided with breakfast. You will collect all your urine over the 24 hours following the sandwich and consume the last day (5^{th}) of the controlled diet. You will return the 4^{th} urine collection to the CRU on the morning of the sixth day. This completes Dietary Phase 1.

Low Oxalate Dietary Phase 2 – Not Colonized with OxF

At least one week after completion of dietary phase 1, you will repeat the procedures above, but with a controlled diet containing a low level of oxalate (50mg) and normal levels of calcium (1000mg).

Colonization with OxF

You will be invited to return to the CRU in the fasted state and provided with breakfast, which will include a sandwich with turkey and a pesto spread enriched in regular spinach and 1 gram of live OxF paste. This protocol has previously been shown to successfully colonize 8 individuals. Before breakfast you will be asked to consume a drink containing sodium bicarbonate to neutralize your stomach acids and help protect the OxF from digestion. You are asked to refrain from any drinks (apart from water) and food for 2 hours following completion of the OxF colonization meal.

You will be asked to provide a stool sample 1 week after ingesting the bacteria to determine whether you are colonized. If you are not colonized, you will be asked to repeat the ingestion of OxF on 2 consecutive days. After colonization is confirmed, you will repeat the dietary studies described above.

Moderately High Oxalate Dietary Phase 3 – Colonized with OxF

As described above in Dietary Phase 1.

Low Oxalate Dietary Phase 4 – Colonized with OxF

As described above in Dietary Phase 2

Stability of Colonization

You will be required to bring in further fecal samples at 6 months and then yearly to determine the stability of OxF in your intestines. You will be asked at these times whether you have taken any antibiotics, or experienced any gastrointestinal issues, including diarrheal disease.
The total number of samples you will be asked to provide will be five blood samples, nineteen 24 hr urine collections, and fourteen stool collections over the course of the dietary phases. You will be contacted at six months and then yearly to ask if you are willing to send in a fecal sample to determine if you are still colonized with OxF. The samples you provide will be used only for research and will not be sold. The total time you may be in this study is 25 days to complete the screening phase and dietary phases. You can stop participating at any time. Compensation for each of the follow-up stool specimens will be $50 per specimen.

Risks and Discomforts

You may experience some discomfort when blood is drawn from your arm. There is a slight risk of a bruise occurring in your arm following these punctures of your veins, and if one does form it should disappear after several days. There is also a slight chance of infection occurring at the injection site or of your fainting during the blood draw. If you do faint, you will be assisted by the nursing staff and rested until you are capable of normal activities.

There is also a risk of illness from improperly handled prepared food. The CRU metabolic kitchen maintains strict policies and procedures to ensure food safety, but you will also need to handle food safely and as instructed to minimize risk.

You should not participate in this study if you are or may become pregnant. If you were pregnant it would not be harmful to you or your baby, but could impact the experimental results.

There also may be other side effects that we cannot predict. Please report any symptoms that arise during the course of this study to study staff.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand how to prevent kidney stones in the future.

Alternatives

This is not a treatment study and your participation is voluntary. Your alternative is to not participate in this research study.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- National Institutes of Health (NIH)
- the Food and Drug Administration (FDA)
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities so costs for clinical services can be appropriately paid for by either the study account or by your insurance.

A description of this clinical trial will be available on http://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 website at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study

will not affect your relationship with this institution or your Urology doctor. Contact the study doctor if you want to withdraw from the study.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

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

Payment for Participation in Research

You will be compensated for each phase you complete as follows: $40 for Screening; $200 for each of the 4 controlled Dietary Phases and $10 for consuming the OxF breakfast. You will be compensated $50 for each follow up stool specimen that you bring in following the dietary study. If you quit the study at any point, you will be paid $10 for each blood, urine and fecal collection. Payment will be made at the end of each phase.

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available and might affect your choice to stay in the study.

Optional Research

The Department of Urology has a very active research program in kidney stone disease with several projects funded by the National Institutes of Health and by research foundations. Patients like yourself are often asked to participate in such studies. Please initial your choice to indicate your willingness to be contacted about such studies.

____ No, I do not want to be contacted.

____ Yes, I am willing to learn about research studies for which I may be qualified.
____ Contact me by mail;____Contact me by phone

Storage of Specimens for Future Use

As part of this study, we would like to store some of the urine, blood and fecal specimens collected from you for future research of kidney stone disease. The future research may be conducted by the study doctor or by other researchers that obtain IRB approval for their research. The specimens will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor. The specimens obtained from you in this research may help in the development of a future commercial product. There are no plans to provide financial compensation to you should this occur. You do not have to agree to allow your specimens to be stored in order to be part of this study.

You may request at any time that your specimens be removed from storage and not be used for future research. If you decide you want your specimens removed, you may contact the study doctor. Once the request is received, and if your specimens have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until used.

Initial your choice below:

___ I agree to allow my specimens to be kept and used for future research on kidney stone disease

___ I do not agree to allow my specimens to be kept and used for future research.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact John Knight. He will be glad to answer any of your questions. John Knight's number is 205-996-2295. He may also be reached after hours at this number.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-800-822-8816. If calling this toll-free number, press the option for an operator/attendant and ask for extension 4-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant	Date
Signature of Principal Investigator or Other Person Obtaining Consent	Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Colonization of healty volunteers with Oxalobacter formigenes and its effects on urinary oxalate excretion

UAB IRB Protocol Number: IRB-131212001
Principal Investigator: John Knight, PhD
Sponsor: NIH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____