LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER in Shreveport
Institutional Review Board (IRB) for the Protection of Human Research Subjects

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of research study: Optimization of blood 25-hydroxy-vitamin D levels in African Americans

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Sponsor: National Institutes of Health, Bethesda, MD

Investigator: Dr. Sushil K. Jain

Contact Information: Department of Pediatrics, Tel 318-675-6086

Participant Name: _____

Participant ID Number: _____

KEY INFORMATION

The following is a short summary of this study to help you decide whether you should participate. More detailed information is listed later in this document.

Why is this research being done and why am I being invited to take part?

Clinical studies have shown that people who have higher levels of 25-hydroxy-vitamin D in blood also experience better health. African Americans have a much higher incidence of 25-hydroxy-vitamin D deficiency primarily due to the fact that pigmentation (darker skin) reduces vitamin D production in the skin. This clinical trial will investigate whether a new approach of supplementation with L-cysteine along with vitamin D will help increase blood levels of 25-hyroxy-vitamin D better than compared to supplementation with vitamin D alone in African Americans. Researchers at LSUHSC hope to find a new therapy to reduce vitamin D deficiency and thereby improve health in African Americans.

You are being asked to take part in this study because you are African American and are between the ages of 18 and 65. As a participant in this study you will also become a research subject. There is no difference between a research subject and a subject not involved in this study in terms of cost or medical care provided.

What should I know about being in a research study?

- You will receive an explanation for this research.
- Your participation is completely voluntary.
- You can stop or leave at any time and your decision will not affect your relationship with this institution or your normal care.

- You will be told about any new information or changes in the study that could affect your health, welfare, or choice to stay in the research.
- You may discuss whether to participate with family, friends and/or your doctor
- You can ask all the questions you want before deciding if you want to be in this study.

WHAT IS INVOLVED IN THE STUDY?

Procedures: If you consent to participate in this research study, we will ask your medical history and any medications you are taking. We will also draw your blood to do medical tests to determine your eligibility to participate in this research. You will give blood only during five clinic visits and during two clinic visits we will also conduct a glucose tolerance test which can tell how efficiently your body utilizes sugar-rich food consumed by you.

Medical Tests:

The blood collection for this study will require needle pricks to your vein, which may cause you minimal discomfort. You may experience some bruising and/or slight soreness at the blood collection site. There should not be any restriction on your normal activities due to participation in this study. No other extra examinations, procedures or tests are required for participation in this study. All participants will agree not to eat anything for about 8 hours before coming to the clinic for blood draw.

Submitting Tissue Blood for Research

By your consent to participate in this research, you authorize the use of your bodily fluids (blood) for research that will be destroyed after the intended use.

HOW LONG WILL I BE IN THE STUDY?

Inclusion/Exclusion Criteria: Subjects with sickle cell disease, any underlying chronic liver disease, or with a positive pregnancy test will be excluded from the study. Any participant who will not agree to stop taking any supplemental vitamins or herbal products, and women who are sexually active and do not agree to use contraceptives, will be excluded. All current and new medications will be reviewed by the investigators and a determination will be made about the participant's continuation.

How long will I take part in this research?

APPROXIMATE TOTAL TIME REQUIRED TO PARTICIPATE IN THE STUDY IS ABOUT SEVEN MONTHS. THE RESEARCHER MAY DECIDE TO TAKE YOU OFF THIS STUDY IF YOU DO NOT FOLLOW DOCTOR'S ORDERS FOR THIS STUDY. FOR EXAMPLE: IF THE PARTICIPANT TAKES ANY NON-PRESCRIBED MEDICATION OR SUPPLEMENTAL VITAMINS OR HERBAL PRODUCTS AND/OR DOES NOT USE PROTECTIVE SAFEGUARDS AGAINST PREGNANCY. IT IS UNLIKELY, BUT THE STUDY MAY BE STOPPED EARLY DUE TO LACK OF FUNDING. IF YOU DECIDE TO TAKE PART IN THIS STUDY, DR. JAIN AND/OR HIS ASSOCIATES WILL DESCRIBE THE PROCEDURES TO BE FOLLOWED, INCLUDING THEIR PURPOSES, HOW LONG THEY WILL TAKE, AND THEIR FREQUENCY.

What will I be asked to do in this study?

---You will also be asked to take two capsules each day containing either vitamin D, L-cysteine or placebo, by mouth for seven months. L-cysteine and vitamin D are normal constituents of our food and their intake have no known harmful effects. Placebo or L-cysteine or vitamin D capsules will be provided to you free of charge during the course of the study. Placebo capsules do not contain vitamin D or L-cysteine but do look like the vitamin D or L-cysteine capsule.

-Subjects will be assigned to either the vitamin D, L-cysteine or placebo randomly. There is a one in four chance you will be assigned to placebo, vitamin D or L-cysteine or vitamin D+L-cysteine combined.

-A serum pregnancy test will be done in female subjects, and if the test is positive then the subject will be withdrawn from this study.

--You will be asked to come to the study clinic for five study visits. We will draw approximately five teaspoons (twenty-four mL) of blood. This will be done a total of five times. Blood will be drawn the first time you are seen, and then after one month, then after two months, four months and six months. You will also fill out questionnaires at each visit.

-We will also do a medical test called a glucose tolerance test during the second and last (fifth) visit. This involves drinking orange juice containing sugar and then giving blood after one and two hours. The amount of blood drawn is only one teaspoon for this procedure.

More detailed information about the study procedures can be found under the PROCEDURE section of this form.

Is there any way this study could be bad for me?

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. Your participation in this study does not involve any known risk. L-cysteine and vitamin D are normal constituents of our food and their intake has no known harmful effects. Your blood will be monitored at each visit to assess any unexpected risk to you during this study. You will be told of any new risks. Significant new findings developed during the course of this research will be provided to you. If you are pregnant, you cannot take part in this study because we do not know how vitamin D and L-cysteine could affect your pregnancy.

Reproductive Risks: The effects of L-cysteine on the unborn fetus are not known. It is very important that you practice birth control to prevent pregnancy during this study. All pregnancies that occur during the study should be reported to the study doctor immediately. Women who are pregnant or nursing are not allowed to participate in the study as the safety of the study drug in pregnancy or nursing children is unknown. If you think you might be pregnant during the study, you must tell the study doctor promptly. If you become pregnant during the study, the study drug will be stopped and you will be asked to complete all the visits described for the Follow-up period. The study doctor will ask to follow the outcome of your pregnancy and the condition of your newborn.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

What Other Options Are There?

An alternative is not to take part in this study. Please talk to your regular doctor about these and other options.

Will being in this study help me in any way?

There is no benefit to you directly from this study but, this research may help increase knowledge of why African Americans have vitamin D-deficiency and find a new therapy, which can help in the management of vitamin D deficiency. We cannot and do not guarantee that you will receive any benefits from this study. This study may offer some benefit to you and others in the future by discovery of a new therapy to reduce vitamin D deficiency and improve health.

What happens if I do not want to be in this research study?

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

Please review the rest of this document for more details and important things you should know if you decide to join. Before you agree to be in the study, please ask the study team to answer all your questions.

DETAILED INFORMATION

Why are you being invited to take part in a research study?

You are being invited to take part in a research study because clinical studies have shown that people who have higher blood levels of 25-hydroxy-vitamin D also experience and have a better health outcome. You are being asked to take part in this study because you are African American and are between the ages of 18 and 65. As a participant in this study you will also become a research subject. There is no difference between a research subject and a subject not involved in this study in terms of cost or medical care provided.

Why is this research being done?

African Americans have a much higher incidence of 25-hydroxy-vitamin D deficiency primarily due to the fact that pigmentation (darker skin) reduces vitamin D production in the skin. Clinical studies have found that vitamin D supplementation alone is not always successful in raising blood levels of vitamin D and reducing insulin resistance. This clinical trial will investigate whether a novel approach of supplementation with L-cysteine along with vitamin D will help increase blood levels of 25-hyroxy-vitamin D and lower insulin resistance better compared to supplementation with vitamin D alone in African Americans. If successful, this will provide a new therapy to reduce vitamin D deficiency and insulin resistance, which may assist in reducing health conditions, such as diabetes, in African Americans.

How long will the research last?

We expect that you will be in this research study for seven months.

How many people will be in the research?

We expect about 150 people to participate in this research at our site.

What happens if I say yes, I want to be in this research?

-We will collect information on your body weight, height, blood pressure and medications you are taking during each clinic visit.

-We will collect your telephone number to call to remind you of your next clinic visit, to check if you are taking your capsules each day, and to check if you have any questions or problems. Dr. Jain or Dr. Levine's, study nurse or qualified staff approved by the School will interact or contact you during the study period.

-The total time of this study is seven months. First, third and fourth visits will each take about two hours of your time. Second and fifth visits will take about 3 hours. It is unlikely, but the study may be stopped early due to lack of funding. Dr. Jain or his associates will describe the procedures to be followed, including their purposes, how long they will take, and their frequency.

-You will also be asked to take two capsules each day containing either vitamin D, L-cysteine or placebo, daily, by mouth during the seven-month study period. L-cysteine and vitamin D are normal constituents of our food and their intake have no known harmful effects. Placebo or L-cysteine or vitamin D capsules will be provided to you free of charge during the course of the study. Placebo capsules do not contain vitamin D or L-cysteine) but do look like the VD or L-cysteine capsule.

--You will be asked to come to the study clinic for five study visits. We will draw approximately five teaspoons (24 mL) of blood. This will be done a total of five times. Blood will be drawn the first time you are seen, and then after one month, then after two months, four months and six months. You will also fill out questionnaires at each visit.

-The blood collection for this study will require needle pricks to your vein, which may cause you minimal discomfort. You may experience some bruising and/or slight soreness at the blood collection site. There should not be any restriction on your normal activities due to participation in this study. No other extra examinations, procedures or tests, are required for participation in this study. All participants will agree not to eat anything for about eight hours before coming to the clinic for blood draw. Participants will not take any non-prescribed medication nor supplemental vitamins or herbal products and will agree to use protective safeguards against pregnancy. If unable to adhere immediately inform your physician. A serum pregnancy test will be done in female subjects, and if the test is positive then the subject will be withdrawn from this study.

-We will also do a medical test called a glucose tolerance test during second and fifth visit. This involves drinking orange juice containing sugar and then giving blood after one and two hours. The amount of blood drawn is only one teaspoon for this procedure.

The study clinic will be located at the Clinical trial office, Ochsner-LSU Hospital, Margaret Place, in Shreveport. We will start enrollment of research participants in January 2021.

Photographs will not be taken of participants in this study at any time.

Our contact or interaction with you will be only for the purpose of this research study.

Will I definitely receive the experimental drug?

No, you will be assigned to either the vitamin D, L-cysteine, vitamin D+L-cysteine combined or placebo randomly. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. There is a one in four chance you will be assigned to the placebo, vitamin D , L-cysteine or vitamin D+L-cysteine group. Neither you nor the study doctor will know which treatment you are getting.

Randomization Statement: Subjects will be assigned to either the vitamin D, L-cysteine or placebo randomly. There is a one in four chance you will be assigned to placebo, vitamin D, L-cysteine or vitamin D+L-cysteine.

What are my responsibilities if I take part in this research?

If you take part in the research, it is important for your safety that you follow all instructions. The researcher may decide to take you off this study if you do not follow instructions/orders for this study. For example: if a participant takes any non-prescribed medication or supplemental vitamins or herbal products and/or does not use protective safeguards against pregnancy you may be withdrawn.

- Follow the directions of the study doctor and research staff.
- Tell your other health care providers that you are in a research study.
- Tell your study doctor and staff about all medications you are taking (prescription and over the counter, and all of your health issues.
- Call the study doctor or staff at _____ if you have any questions.

What are my other options if I do not want to be in this research?

You do not have to be in this study. If you decide not to be in the research now or later, it will not affect your usual care and it won't be held against you.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you will not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below. If you decide to stop, we may ask you if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

Can I be removed from the research without my OK?

The doctor in charge of the research study or the sponsor can take you out of the study even if you do not ask to leave. The researcher may decide to take you off this study if you do not follow instructions/orders for this study. For example: if the participant takes any non-prescribed medication or supplemental vitamins or herbal products and/or does not use protective safeguards against pregnancy.

What are the risks of being in this study?

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. Your participation in this study does not involve any known risk. L-cysteine and vitamin D are normal constituents of our food and their intake have no known harmful effects. Your blood will be monitored at each visit to assess any unexpected risk to you during this study. You will be told of any new risks. Significant new findings developed during the course of this research will be provided to you. If you are pregnant, you cannot take part in this study because we do not know how vitamin D and L-cysteine could affect your pregnancy.

For breach of confidentiality: The only risk of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

The risks of having blood drawn include slight pain when the needle is inserted. You may develop bruising, and your arm may be sore. Occasionally, some people feel dizzy or lightheaded when blood is drawn. They may become sweaty, feel cold or tingly, and may faint or throw up. Risks that are possible but unlikely include infection, nerve damage, and puncturing an artery instead of a vein.

If you are a woman who is able to have children, you must have a negative pregnancy test before you start the study and you must agree to use effective birth control.

If you become pregnant during the study, you should tell the study doctors.

What are the costs of being in the research?

Tests and procedures will be done solely because you are in the research study are not considered ordinary care. The research specific costs will be at no charge to you or your insurance company.

Will being in this study help me in any way?

You will be paid $50 for each visit during this study period to cover your transportation or other expenses. This is done because you will need to come to clinic for blood draws required for the research study. You will not be given any other monetary compensation for taking part in this study. The tests performed during the research study will be at no charge to you and will be paid by the study sponsor. However, you or your insurance company must pay for all tests and procedures that are not part of the study, but that your doctors feel are needed to help you.

If your medical condition requires that you receive certain standard medical tests and procedures. These standard tests and procedures will be charged in the usual way. Tests and procedures done solely because you are in the research study are not considered ordinary care. The research specific costs will be at no charge to you or your insurance company.

In accordance with federal regulations, we are obliged to inform you about the policy of LSUHSC-S in the event of an adverse reaction. LSUHSC-S will provide medical care for any adverse reactions directly resulting from your participation in approved LSUHSC-S research. However, we have no voluntary program of compensation for research-related injuries (loss of wages, etc). Further information can be obtained by calling the Human Research Protection Program at (318)-813-1350.

Will my information collected for the research remain confidential?

Any information obtained during this study that identifies you as a subject will remain confidential and will be disclosed only with your permission. Because this study involves articles regulated by the FDA (Food and Drug Administration) the FDA may choose to inspect records identifying you as a subject in this investigation. Your information, in all cases, will be treated as confidential except as otherwise prohibited by federal or state law. The results of this research may be used or reported in a scientific presentation or publication, but you will not be personally identified and confidentiality will be maintained.

We may use or share your research information and/or biospecimen for future research studies, but it will be deidentified, which means that it will not contain your name or other information that can directly identify you. Future research may be similar to this study or completely different. We will not ask for your additional informed consent for future studies. We may also share your deidentified information and/ or biospecimen with other researchers at Ochsner LSU Health Shreveport Academic Medical Center (Ochsner LSU Health Shreveport St. Mary Medical Center) or at other institutions.

The sponsor, monitors, auditors, the LSUHSC-S HRPP, Ochsner LSU Health Shreveport Academic Medical (Ochsner LSU Health Shreveport St. Mary Medical Center) and/or Ochsner LSU Health Monroe Medical Center, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

What else do I need to know?

--It is important that you tell your researcher, Dr. Jain or Dr. Levine, if you think you have been injured or have experienced a medical problem as a result of taking part in this research study. You can tell them in person or by phone at 318-675-6086.

--Medical treatment for an injury or illness related to your participation in this study will be made available to you by LSU Health Sciences Center at Shreveport and Ochsner LSU Health Shreveport Academic Medical (Ochsner LSU Health Shreveport St. Mary Medical Center) and/or Ochsner LSU Health Monroe Medical Center. Generally, this care will be billed to you, your insurance, or other third party. We have no program to pay for medical care for research-related injury.

--If you agree to take part in this research, we will pay you 50 dollars for each clinic visit for your time and effort.

--We may learn things about your health as part of this research that may affect your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise to help you learn more about your research results. You can discuss this information with your doctor.
--Data or biospecimens collected from you for this research may be used to develop new tests, drugs, or devices. Your samples may be used for commercial profit and there is no plan to share these profits with you.
--A description of this clinical trial will be available on https://ClinicalTrials.gov, as required by the US Law. The description will not include information that can identify you. At most, the website will include a summary of the results.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team or Dr. Jain or Dr. Levine. (318-675-6086)

This research has been reviewed and approved by the LSUHSC-S IRB which is a group of people who help protect your rights and welfare as a research participant. You may also talk to them at (318) 813-1350 about:

- Questions, concerns, or complaints that are not being answered by the research team.
- Concerns if you cannot reach the research team.
- The need to talk to someone besides the research team.
- Any questions about your rights as a research subject.
- The desire to get more information or provide input about this research.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date/Time (AM or PM)
Printed name of subject	
Signature of person obtaining consent	Date/Time (AM or PM)
Printed name of person obtaining consent	
Signature of witness to subject's signature	Date/Time (AM or PM)
Printed name of person witnessing subject's signature	