INFORMED CONSENT FORM

Official title: Vitamin D Deficiency in Adults Following a Major Burn Injury

NCT number: NCT05084248

IRB Approved date: 10-19-22

Title of Study: Vitamin D Deficiency in Adults Following a Major Burn Injury

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center
Parkland Health & Hospital System

Key Information about this Study

The purpose of this study is to identify the incidence of Vitamin D deficiency after a major burn injury. We would also evaluate the effects of replacing Vitamin D on the common conditions associated with burn injury, like fatigue, pain, itchiness, and tingling/numbness on different parts of the body (peripheral neuropathy).

Participants in this study will be seen twice (during either of the regular 6-, 12-, 18-, 24-, or 30-month post-burn injury visits) at the outpatient burn clinic. You will also be asked to complete a questionnaire. A blood sample will be collected. You will then be given a bottle of Vitamin D pills that will be taken for 6 months. We will call you monthly to check on side effects and to remind you to take the pills. On the 12-month post-enrollment visit, we will again ask you to complete the questionnaires and have a blood draw for Vitamin D levels. You will also be asked to return the bottle with any unused Vitamin D pills.

If you decide to participate in the study, please be aware that any time information is collected, there is a potential risk of loss of confidentiality. Every effort will be made to keep your confidential information secure; however, this cannot be guaranteed.

If you are interested in learning more about this study, please continue to read below.

Information about this form

If you are providing consent for someone else, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow, the word “you” refers to the person you are providing consent for.

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor is a research investigator in this study. She is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern and Parkland staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

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General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Dr. Karen Kowalske, M.D., professor at the Department of Physical Medicine and Rehabilitation at UT Southwestern Medical Center and Parkland Health and Hospital System.

Funding
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), a federal agency that promotes scientific research, is funding this study. This organization is providing money to UT Southwestern Medical Center and Parkland Health and Hospital System so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

We would like to know how common Vitamin D deficiency is, after a major burn injury. We would also like to compare the effect of taking low dose Vitamin D pills to high-dose Vitamin D pills on the blood levels of Vitamin D in adult patients with major burn injury, and if it improves common burn-related symptoms such as fatigue, muscle weakness, pain, itch, and tingling/numbness of different parts of the body (peripheral neuropathy).

You are asked to participate in this research study of Vitamin D deficiency among major burn injury patients.

This study will help find out what effects, good and/or bad, Vitamin D has on people who take/use it and on its effect on low Vitamin D levels. The safety of Vitamin D in humans has been tested in prior research studies; however, some side effects may not yet be known.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you have had a burn injury over 4 months ago that either affected more than 10-20% of your total body surface area, or was due to high voltage or lightning, or it involved the hand and/or face and/or feet and you were referred for wound closure to Burn Surgery.

How many people are expected to take part in this study?
This study will enroll approximately 60-70 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 7 visits with the researchers or study staff. It may be necessary for you to return to the clinic twice (the first one at either 6-, 12-, 18-, or 24-months post burn injury, and the last one at either 12-, 18-, 24-, or 30-month post-injury). The visit will take place on the same date that you will be coming in for your regular clinic follow up.

Neither you nor the researchers will know which dose you will be receiving. In the event of an emergency, there is a way for the researcher to find out which you are receiving.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Many of the procedures are described below as

"**standard care**" and would be done even if you do not take part in this research study. You will be told which ones are for "**research only**".

Screening Procedure

Blood draw – Blood will be taken from a blood vessel in your arm to measure the level of Vitamin D in your blood

The research procedures will add approximately 30 minutes to the length of a routine care visit.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options.

Assignment to Study Groups –
When it is determined that you are eligible for the study (i.e., your blood Vitamin D level is below 30 ng/mL), you will be assigned by chance (like flipping a coin) to receive either: lower dose (400 IU) Vitamin D or higher dose (4000 IU) Vitamin D.

Study Procedures - as a participant, you will undergo the following procedures:

- Clinic Visit 1: **Screening / Enrollment visit, either 6-, 12-, 18-, or 24-months post-burn injury (± 2 months)**
  - Review the inclusion / exclusion criteria
  - If you are enrolled in the Burn Model System study, we will get your answers from the following questionnaires at this time; if you're not part of the Burn Model System study, you will fill out the following questionnaires:
    - PROMIS-29
    - PROMIS-Global
    - PROMIS-Itch
  - You will be asked about your treatments and compliance, sun exposure, and diet
  - You will receive a call from us with the result of your Vitamin D level. If your level is below 30ng/mL, you will receive a bottle of Vitamin D pills with instructions on how to take them and contact information for any questions or concerns you may have.

- **Monthly safety phone calls**
  - We will call you once a month for the next 5 months to ask about adverse events
  - We will also remind you to take the Vitamin D

- Clinic Visit 2: **End of study visit, either 12-, 18-, 24-, or 30-months post-burn injury (± 2 months)**
  - Return bottle of pills (with unused pills)
  - If you are enrolled in the Burn Model System study, we will get your answers from the following questionnaires at this time; if you're not part of the Burn Model System study, you will fill out the following questionnaires:
    - PROMIS-29
    - PROMIS-Global
    - PROMIS-Itch
  - Blood draw for Vitamin D level

Could your participation end early?
There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.

- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. Clinically relevant results of the research will be communicated to you at the end of the study. Clinically relevant means that the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable and it can be confirmed. In that case, we will attempt to notify you using the contact information you have provided.

If you do not want to be notified of any of these incidental findings, please initial below.

_____ Please do not notify me of any incidental findings obtained from this research.

Risks – "What are the risks of participation in the research?"

Risks from the research
The investigators have designed this study to learn how well the new treatment(s) compare to commonly accepted treatment(s). You may get a treatment or drug that does not help treat your disease or that makes your condition or disease worse.

Risks from the specific research procedures and study drug
There are risks to taking part in this research study. One risk is that you may have side effects while on the study.

Side effects from this study will usually go away soon after you stop taking the Vitamin D. In some cases, side effects can be long lasting or may never go away.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Blood Draw
Discomfort
Bruising

Questionnaires
Discomfort

Vitamin D
There are no known risks at the doses prescribed in this study. Taking 47x this dose produced one case in 20,000 patients. Symptoms were fatigue, nausea, and slurred speech.

The study doctors don't know all the side effects that may happen. Everyone taking part in the study will be watched carefully for any side effects. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes returning

the bottle of pills with unused pills, answering questionnaires and a blood draw for Vitamin D level. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, [or even at different times,] may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is improvement in bone density and immune function. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include:1) getting treatment or care without being in a study or 2) getting no treatment

Payments – Will there be any payments for participation?

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of study procedures. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

You will be given $25 on Visit 1 and $75 on Visit 7, for a total of $100.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as other tests (like x-rays or blood tests other than Vitamin D level) that your provider asks for during your regular visit or any other prescribed drugs. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures, you will be required to pay for them.

Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research).

The sponsor will provide the study drug free of charge during this study. At the end of your participation you must return all unused study drug/device to the researcher.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

How will my information and/or tissue samples be used?
With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

HIPAA Section:
Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:
your medical history and blood work, information that we get from your medical record, information contained in your underlying medical records related to your medical history and treatments prior to the study, information that is created or collected during your participation in the study including medical and treatment history, information you give us during your participation in the study such as during interviews or from questionnaires, results of blood tests; demographic information like your age, sex, and ethnicity.

We will get this information by asking you, asking your doctor, by looking at your chart at Parkland Health and Hospital System.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor, NIDILRR, funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center, Parkland Health and Hospital System.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of UT Southwestern and Parkland for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Dr. Karen Kowalske, 5323 Harry Hines Blvd., Mail Code 9055, Dallas, TX 75390-9055. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?

By signing this form, you agree to let us use and disclose your health information for purposes of the study until the study has been completed (closed). This permission to use your personal health information expires on the date noted above.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact the following:

Primary contact:
Karen J. Kowalske, M.D. can be reached at 214.645.2080 (weekdays and weekends)

If primary is not available, contact
Kyra Jeanine Solis can be reached at 214.648.3560 during regular office hours.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments, or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

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Surrogate Signature Section

Printed Name of Participant	Signature of Participant Giving Assent (*If incapable of signing, person obtaining consent should initial here*)	Date	Time AM PM
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Witness / Interpreter Signature Section

Interpreter/witness (Interpreter signature required per hospital policies when physically present.)
I attest that I have interpreted the information in this consent form and it was explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of Interpreter	Signature of Interpreter	Date	Time AM PM

Witness Signature (required when interpreter is not physically present-e.g., Language Line is used):
By signing below:
I attest that the information in the consent form was accurately explained to, and apparently understood by the subject or the subject's legal authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative as indicated by their signature on the associated **short form**.

Printed Name of witness	Signature of witness	Date	Time AM PM

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Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM