Randomized Controlled Trial of Vitamin D to reduce racial disparity in chronic pain following Motor Vehicle Collision: The VENTURE Trial (Vitamin D to ENhance TraUma Recovery)

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INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY AND HIPAA AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

CONSENT FORM
FORM VERSION DATE: 8.29.23

TITLE: Randomized Controlled Trial of Vitamin D to reduce racial disparity in chronic pain following Motor Vehicle Collision: The VENTURE Trial (Vitamin D to ENhance TraUma REcovery)

UNC STUDY NUMBER: # 21-2589

SPONSOR/FUNDING SOURCE: National Institutes of Health (NIH)/University of North Carolina

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STUDY-RELATED PHONE NUMBER(S): (856) 342-2637

Participant Name: _____ Date of Birth: _____/_____/____

Concise Summary

This is a research study to find out if vitamin D can help people recover from musculoskeletal pain (MSP) in the months following a car accident. In this study, we will ask that you complete an initial survey during your stay in the emergency department that will assess your initial pain following your car accident, as well as learn more about parts of your previous medical history. If you consent to be part of this study, we will ask for small blood samples from you today and in 3 months to determine the vitamin D levels in your body. After today, we will ask you to complete surveys 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 9 weeks, and 3 months from today. These surveys can be completed on your smartphone, computer, or over the phone. There are risks to taking vitamin D that are described in this document. Side effects of vitamin D are rare but include headache, decreased appetite, dry mouth, metallic taste, and nausea/vomiting. If you agree to take part in this research study, there may not be a direct medical benefit to you.

We hope the information learned from this research study benefit participants and future MVC survivors and improve pain and general health outcomes. If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn about how people recover from musculoskeletal pain (MSP) following a car accident. You are being asked to be in the study because you received services through the emergency department and meet all eligibility criteria, which are listed below. The information gathered in this study will be used to help improve the care of individuals recovering from car accidents and other musculoskeletal injuries in the future. The use of Vitamin D is approved by the FDA. However, it is being used for a new indication in this study and therefore its use in this study is considered investigational or not approved by the FDA. As part of this research, we are conducting surveys with participants seen at the emergency room after a car accident. During these surveys, we would like to find out about your overall health and well-being. You are being asked to be in the study because you received services through the emergency department, own a smartphone, have an email address, are willing to provide a blood sample, are willing to receive text messages, and are between the ages of 18-65. You will participate in the study today and for the next 3 months.

Are there any reasons you should not be in this study?
You should not be in this study if you are not willing to take vitamin D. You should not be in this study if you are pregnant or breastfeeding, are a prisoner, have known chronic kidney disease stage 4 or higher, have known hypercalcemia, take vitamin D supplements in excess of 800 IU daily, or do not speak and read English fluently. You should not participate in this study if you require(d) admission to the hospital, have a fracture, have a laceration with significant

hemorrhage, have an intracranial injury, have a self-inflicted injury, you have acute psychosis, thoughts of suicide, or harming others (homicide), experience ongoing domestic violence, or exceed the acceptable level of chronic daily opioid use (≥13mg oxycodone or equivalent). You should not be in this study if you are not non-Hispanic White and non-Hispanic Black.

How many people will take part in this study?

Approximately 90 people will be enrolled in this trial across four sites. Approximately 25 people will be enrolled at Cooper University Hospital.

How long will your part in this study last?

Your participation in the study will last for 3 months. If you choose to participate in the study, we will interview you for approximately 1 hour during your emergency department visit today. Over the next 3 months, you will be asked to complete 6 follow-up surveys which will take place in 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, and 3 months from today. The surveys occurring at weeks 2, 4, and 5 will be brief and will take you approximately 10 minutes to complete. These brief surveys will be sent to you via text messages and can be completed on REDCap, a smartphone-accessible, secure survey website. The surveys occurring 3 weeks, 4 weeks, and 3 months from today will take you approximately 30 minutes each to complete. We will ask you to update your contact information 9 weeks from today which will take about 5 minutes to complete. All surveys can be sent to your email or cell phone number to be completed online (on REDCap) or can be completed over the phone. Finally, 3 months from today, you will be asked to put a small (3 drops) blood sample onto a blood spot card via a fingerstick. You will send this prepaid and pre-addressed card to the study team by dropping it in the mail.

What will happen if you take part in the study?

Your participation in this study will not affect your treatment plan between you and your physician. After reading and signing this consent form, your participation will begin with the initial interview during which an initial baseline assessment will be administered. You may refuse to answer any of these questions. After this initial assessment, we will ask for you to provide a small blood sample which we will use to check the vitamin D levels in your blood. This blood sample will be obtained using a fingerstick with a small, sterile lancet. If you are having blood drawn for lab work during your visit in the emergency department, you may choose to consent to having your blood sample taken from this blood draw. Following the collection of the blood sample, you will be asked to fill out a baseline questionnaire. This questionnaire will collect information regarding your demographic information (e.g. age, sex, race), the details of your pain following your car accident, and information regarding medications you may be taking. After you have completed the questionnaire, you will be randomized into one of two groups, either the group receiving vitamin D or the placebo. This selection is based on chance, and you or your treating physician will not know which group you are assigned to. A urine pregnancy test will be done on all females who might be able to get pregnant at the start of the study. The cost of the pregnancy test of applicable participants will be covered by the study.

If you agree to participate in the study, we will provide you with instructions on follow-up surveys which we will ask you to complete 2 weeks, 3 weeks, 4 weeks, 5 weeks, 6 weeks, 9 weeks, and 3 months from today. Additionally, you will be provided with the supplies and instructions to complete a fingerstick blood draw, similar to the one that will be done in the emergency department today, at home 3 months from today. You will then send this prepaid and pre-addressed card to the study team by dropping it in the mail. If you happen to misplace these materials before the end of the 3-month period, we will send you a replacement kit to your home.

What are the possible benefits from being in this study?

If you agree to take part in this research study, there may not be a direct medical benefit to you. We hope the information learned from this research study will benefit other patients with who have been involved in a motor vehicle accident in the future. Potential benefits to you may include more frequent than usual medical exams/assessments.

Studies that use specimens from this repository/biobank may provide additional information that will be helpful in understanding the recovery process after a motor vehicle collision and may contribute to identifying better treatments for people who experience pain after motor vehicle collision.

What are the possible risks or discomforts involved from being in this study?

Interviews: We will be collecting data about your injury and your overall health; every attempt will be made to protect this information. There is a very small risk of a breach of confidentiality during this study. This risk will be minimized by keeping your information on a secure database (REDCap), training of research personnel involved in the study, and we will de-identify your personal information on blood samples.

Blood draws: Very rarely, drawing blood from a finger stick may cause discomfort, bruising, prolonged bleeding, and infection at the site of puncture. To minimize risk, we will swab the site of puncture with alcohol to disinfect the area, use disposable lancet and capillary tubes to collect blood, and apply pressure to the puncture site following the blood draw to minimize bruising. We will cover the puncture with an appropriate dressing.

Emotional Discomfort Risks: You will be asked to answer questions regarding the nature of your accident and the pain you have experienced as a result, which may cause some emotional discomfort or distress. You may choose not to answer any questions you find too distressing.

Consumption of Vitamin D: The use of Vitamin D is approved by the FDA. However, it is being used for a new indication in this study. Vitamin D is safe, well-tolerated, and widely available. Consumption of Vitamin D has been shown to be safe in previous studies. The risk of taking this supplement is small. Side effects of Vitamin D are rare, but include headache, decreased appetite, dry mouth, metallic taste, and nausea/vomiting.

If you experience any discomforts, inform the study doctor immediately.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

If you choose not to be in the study, what other treatment options do you have?
You do not have to participate in this study to receive treatment of your symptoms from the motor vehicle accident. While you are in the study your study doctor can recommend the best treatment for your symptoms.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Records of your participation in this study will be secured in the data coordinating center. No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety. We may use de-identified data and/or specimens from this study in future research without additional consent.

A federal law called the Genetic Information Nondiscrimination Act (GINA) states that it is illegal for covered entities to disclose genetic information about their applicants, employees or members without consent. There are limited exceptions; however, in general, such entities must keep the individual's genetic information confidential. A New Jersey law called The Genetic Privacy Act states that a person's genetic information is private property and cannot be collected, retained, or disclosed without written consent. Under both of these laws, it is illegal for health insurance companies and employers to require anyone to give these companies genetic information about another person without the other person's written consent. The federal and New Jersey laws also state that if an insurance company or employer should somehow obtain genetic information about a client or employee, it is illegal for them to use the genetic information to discriminate against that client or employee. Insurance companies may not use any genetic information they might obtain to make decisions about coverage, rates, or preexisting conditions. Employers may not use any genetic information that they might obtain for decisions about hiring, firing, or promotion.

The federal law does not cover life, disability, or long-term care insurance. For example, life insurance companies may in the future decide to ask if you have ever had genetic tests for cancer susceptibility when you apply for a new policy. However, the New Jersey law prohibits

companies that sell life, disability, or long-term care insurance from using genetic information for unfair discrimination.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

To help us protect your privacy, we have a Certificate of Confidentiality from the FDA. With this Certificate, we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, except when release of that information is required for auditing or evaluation of federally funded projects or to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research, as you are free to do that at any time. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information. In the event that information regarding intent to harm yourself or others, including child abuse, becomes known to us, we are required by law to divulge this information even without your consent.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

If you think you have been injured from taking part in this study, call the study team at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

If you believe that you have been injured or become ill because you took part in this study, you should call the Chief Medical Officer or their representative at (856) 342-3071.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however, no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?

You will be compensated up to $420 for completing study activities. The below table provides an overview of the study activity and what you can earn for completing it.

Study Activity	When Available	Number Available Throughout Participation	Payment Per Completion	Total Possible Payment for Completing All
Blood Draw	Day of Enrollment	1	$10	$10
Brief “Flash” Surveys	2 weeks, 4 weeks, 5 weeks	3	$20	$60
Surveys	3 weeks, 6 weeks, 3 months	3	$60	$180

Updating Contact Information	9 weeks	1	$10	$10
3 Drops of Blood on Card	3 months	1	$60	$60
Total				**$320 + Bonus**

In addition to receiving payments for completing study activities, you can also receive bonus payments for completing the majority of the study activities.

Bonus Payments	
Number of Missed Study Activities	**Bonus Amount**
0	$100
1	$80
2	$60
3	$30

These payments will be sent to your email via electronic gift cards following your enrollment in the emergency department. Electronic gift cards will be sent within the two weeks after completing a study activity. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

Your name, address, and U.S. tax payer identification number (SSN or ITIN) are required to process payments and/or to report taxable income to the IRS. You must complete a W-9 (for U.S. persons) or W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents (for non-resident aliens) in order to receive payment for participation.

U.S. person participants must complete Form W-9 in order to receive payment for participation. If payment by UNC equals or exceeds $600 per calendar year for U.S. persons, UNC will report the amount to the Internal Revenue Service on Form 1099. Nonresident alien participants must complete Form W-8BEN and the Foreign Vendor Withholding Assessment with supporting documents in order to receive payment for participation. Payments to nonresident alien participants may be subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.

If you do not provide your SSN or ITIN, or complete the appropriate documentation noted above, we cannot issue you a payment for participation. However, you may still choose to participate in this study.

Will it cost you anything to be in this study?

It will not cost you anything in addition to what you will be billed for your routine medical care to be in this study. All tests, visits, or procedures other than what is done for this study will be

related to medical care that is part of the usual care for your condition and would be suggested even if you decided not to be in the research study. Examples of standard medical care that may be performed include ECGs (electrocardiogram, which is a painless test to measure the electrical activity in your heart), a pregnancy test, X-Ray, CT scan, MRI, or other imaging, etc.

Who is sponsoring this study?
This research is funded by the National Institute of Health (NIMHD), the UNC Department of Anesthesiology, and the Institute for Trauma Recovery. This means that the research team is being paid by the sponsors for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

You may contact the Cooper Human Research Protections Program (HRPP) if you have questions about this research or about your rights as a research participant at (856) 757-7832. The mailing address of the Cooper HRPP is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. You may contact the HRPP (a) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (b) if you believe that you are being forced to stay in this study when you do not want to, or (c) you have any complaints about the research.

HIPAA AUTHORIZATION

We call your health information that identifies you your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). If you sign this form, you are giving the investigators, their staff, and certain other people described in this form your permission to use your protected health information for this research study.

What information about you will be collected or used?

To do this research, we will collect information about you and your health conditions. Some information about you will also be collected from your medical records. The information collected will be used to determine if you qualify to participate in this research, to follow your treatment and contact you, and to answer the research questions.

The following PHI will be collected or used as part of this research study:

- Identifiers such as your name, medical record number, and contact information
- Personal medical history including present and past medications
- Results of exams, procedures, and tests you have before and during the study
- Your social security number may need to be collected in order to process your study payments
- Social history including tobacco, drug and alcohol use
- Research Study records

Who will use or have access to your protected health information?

By signing this form, you are allowing the following people or groups to have access to your PHI:

- The research team, which includes the investigator listed on this form and other personnel involved in this study, in order to support the study and analyze the data.
- Others employed or contracted by Cooper, if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study may be added to your electronic medical record.
- Cooper's Human Research Protections Program, including the IRB, may look at your study records to ensure the research is being conducted appropriately.

All of these people and entities are obligated to protect your PHI.

You are also allowing your PHI to be used by or shared with other people or groups specified below:

- The Office for Human Research Protection (OHRP). OHRP is an office that oversees research funded by the federal government and oversees the IRB at Cooper University Hospital.
- The National Institute of Health (NIH). The NIH may need to be sure the records are accurate and that the research is done according to NIH regulations.

- UNC, the study sponsor, and its agents or contractors, who may need to access your PHI in order to monitor the study, to ensure that the research records are accurate, and to analyze the research data.

Although these entities listed above have their own confidentiality procedures to protect your PHI, they are not covered by the same federal privacy rule, HIPAA, that governs healthcare providers, and therefore they are not bound to its regulations.

How will your information be kept confidential?

To help maintain the confidentiality of your study records, we will replace your name and any identifying information with a code. Your identifying information will be stored securely and separately from the rest of the research records. All study documents will be stored in a locked file cabinet or in a password-protected secured electronic environment. Only authorized study personnel will have access to your identifiable information.

We may publish the information from this study in scientific journals or present it at scientific meetings, but you will not be personally identified in these publications and presentations. It is possible that the data collected for this study may be useful for future research conducted at Cooper or by other investigators outside of Cooper. We will remove all of the information that identifies you, such as your name. This de-identified data may be used or shared with other investigators for future research studies without additional informed consent from you.

Please note: Healthcare providers are required to share with the New Jersey Department of Health any confirmed diagnosis of over 70 communicable diseases, including but not limited to HIV/AIDS, Hepatitis, Measles and others (N.J. Admin. Code § 8:57-1.5). If in the course of this study, you are diagnosed with any of the diseases listed under New Jersey law, your name, address, and phone number will be shared with the Department of Health. In addition, under New Jersey Law (N.J. Admin. Code § 8:40-3.7) there is a requirement for certain individuals to report any reasonable belief of child or elder abuse to the New Jersey Department of Health (DOH), and in the case of child abuse, the Division of Child Protection and Permanency (DCPP). If in the course of this study, there exists a reasonable belief of child or elder abuse then relevant contact information will be shared with New Jersey DOH and DCPP as required by law.

Do you have to give authorization for use of your PHI?

No, but if you do not give this authorization then you cannot join the study. This will not affect the medical care that you receive outside of the study.

How long will your information be collected, used or shared?

Your authorization for the collection, use, and sharing of your PHI for this specific study does not expire.

Please note that Cooper may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The Institutional Review Board grants permission
- As permitted by law

What if you change your mind?

You may revoke this authorization to use and share your PHI at any time by contacting the principal investigator, in writing, at the address listed on the first page of this form.

If you decide not to authorize the investigator to use and disclose your PHI or you revoke this authorization, you will no longer be able to participate in this research study, and the use or sharing of future PHI will be stopped. However, the PHI that has already been collected may still be used.

Consent/HIPAA Authorization Signature Section:

Signature Page for Adult Subjects

SUBJECT:

Printed Name of Subject: _____

Signature: _____ Date: _____ Time: _____

INVESTIGATOR: I have discussed the study described above with the subject.

Printed Name of Investigator Obtaining Consent: _____

Signature: _____ Date: _____ Time: _____

WITNESS:

Printed Name of Witness to Subject's Signature: _____

Signature: _____ Date: _____ Time: _____