Official Study Title:
A Pilot Study of Vitamin D Replacement in Patients with Non-Hodgkin's Lymphoma or Chronic Lymphocytic Leukemia with Low Vitamin D Levels

ClinicalTrials.gov Identifier (NCT Number):
NCT02553447

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Sponsor / Institution:
University of Nebraska Medical Center

Principal Investigator:
Julie M. Vose, MD

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Consent form

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CONSENT FORM

Title of this Research Study

Invitation
You are invited to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Why are you being asked to be in this research study?
You are being asked to be in this study because you have non-Hodgkins lymphoma or chronic lymphocytic leukemia that is untreated or has not been treated with more than two cycles of chemotherapy or localized radiation therapy.

What is the reason for doing this research study?
This study is being done to determine if a vitamin D supplement given to adults with low levels of vitamin D in their blood affects survival for subjects receiving "wait and watch" or standard of care chemotherapy for the treatment of non-Hodgkins lymphoma or chronic lymphocytic leukemia.

The medication used in this study is a vitamin D supplement available over the counter.

About 312 people will take part in this study.

What will be done during this research study?
Investigators will review your medical history, current medications, and previous treatment for your cancer to determine if you might qualify to participate in the study. If you choose to sign this informed consent form, you will continue with the screening process. Many of the tests are the same as those you have had in the past to diagnose and treat your disease. Some of these same tests will also be done during your treatment to follow your progress. The screening process may take place over a period of up 4 weeks. These may take more than one visit and will include the following:

- A physical examination will be performed.
- Blood tests to evaluate your vitamin D levels and calcium levels

If you have a **normal** level of vitamin D at time of enrollment you will be automatically enrolled in the control group and will be followed only for long-term survival and outcome. No further blood tests for vitamin D levels will be obtained. If you are currently taking Vitamin D supplements you are encouraged to continue with your Vitamin D supplementation.

If you have **low levels** of vitamin D at time of enrollment you will be selected to receive either vitamin D 5000 IU (5 tablets) daily or vitamin D 1000 IU (one tablet) daily for 3 years (1095 days). You will be asked to fill out a medication diary for the Vitamin D. If you are currently taking Vitamin D supplements/medication at the time of screening you will need to discontinue the use of your home supply of Vitamin D and use only the Vitamin D medication/dosing and supply provided to you by the study.

At 6 months, 12 months, year 2 and year 3 (+/- 30 days) after you start Vitamin D, we will review your current medications. You will also have repeat blood tests to evaluate your vitamin D levels. This will be done at the same time you have your blood drawn for your standard evaluations. Based on these vitamin D blood levels you may have your dose of vitamin D adjusted by the investigator. After year 3 (1095 days) the investigator will discuss continuation of Vitamin D supplementation recommendations with you. The supply of any
recommendations for continued Vitamin D will be at your cost.

What are the possible risks of being in this research study?
You may have side effects while on the study. While taking part in the study you will be watched carefully for any side effects. Side effects may occur that have not previously been reported. Side effects may be mild or very serious. The health care team may give you medicines to help lessen side effects. Many side effects go away soon after treatment is stopped. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death. You are encouraged to talk to the investigator about any side effects that you may have while taking part in the study.

Vitamin D
Most people do not commonly experience side effects with vitamin D, unless too much is taken. Some side effects of taking too much vitamin D include:

- fatigue
- nausea
- vomiting
- hypercalcemia

- hypercalciuria
- hyperphosphatemia
- suppressed parathyroid hormone
- weakness
- fatigue
- sleepiness
- headache
- loss of appetite
- dry mouth
- metallic taste
- increase the risk of hardening of the arteries in people with serious kidney
- disease
- kidney stones

As with any medication, allergic reactions are a possibility.

Risks of Study Procedures/Tests

- ***Blood Drawing:*** Some known risks, although rare, are associated with placing needle into a vein or under the skin (when blood samples are taken). These include the possibility of infections, inflammation, a hole poked through the other side of the vein by the needle, bleeding, discomfort, pain, bruising, and a change in skin color at the site. Fainting may occur shortly after having blood collected.

Other and Unknown Risks:
It is possible that other rare side effects could occur which are not described in this protocol. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits to you?
It is possible that your participation in this study may result in promoting normal Vitamin D levels which are associated with improved bone health and possibly improved survival in patients with NHL and CLL. However, you may not get any benefit from being in this research study.

What are the possible benefits to other people?
Information obtained from this study may help subjects in the future with the same disease by contributing to the knowledge of vitamin D levels in cancers, and to understand the potential clinical benefit of this regimen.

What are the alternatives to being in this research study?

Standard therapy for low vitamin D levels as per your primary doctor may include no evaluation of vitamin levels or treatment recommendations may or may not be similar to treatment as described in this research study. Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?
You and/or your health plan/insurance company will need to pay all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

The study will pay for the 3 year supply of vitamin D tablets as well as the handling of the optional research blood sample handling and storage.

The clinically indicated tests and procedures (laboratory tests, radiology tests, and physical examinations) will be your responsibility or your health insurance company's responsibility as these are considered standard cancer treatment. You or your health insurance company might also have to pay for other drugs or treatments that are given to help you control side effects.

You will be responsible for any applicable insurance deductibles and co-payments.

If you wish to speak with a financial counselor about your insurance coverage and benefits, let the investigator or other study personnel know. A contact for personal assistance will be made available for you.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at:
http://cancer.gov/clinicaltrials/understanding/insurance-coverage

You can print a copy of the Clinical Trials and Insurance Coverage information from this Website.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
This research is being paid for by the Fred & Pamela Buffett Cancer Center and the Center for Clinical & Translational Research support at the University of Nebraska Medical Center.

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

Emergency medical treatment for this injury or problem will be available at the Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider.

The Institution has no plans to pay for any required treatment or provide other compensation. If you have insurance, your insurance company may or may not pay the costs of medical treatment. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay for the medical treatment.

Agreeing to this does not mean you have given up any of your legal rights.

How will information about you be protected?
You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

Who can see information about you?
By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your PHI, as necessary, with other

people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
  - The HHS Office of Human Research Protections (OHRP)
  - The Food and Drug Administration (FDA)
  - National Institutes of Health (NIH)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
  - Your health insurance company
  - The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. There is currently no plan to end this study. Your information may be kept and used indefinitely.

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Julie M. Vose, MD
University of Nebraska Medical Center
987680 Nebraska Medical Center
Omaha, NE 68198-7680

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 will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the Institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff.

Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled.

For your safety, please talk to the research team before you stop taking any study drugs or stop other related procedures. They will advise you how to withdraw safely. If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests.

You may be taken off the study if you do not follow instructions of the investigator or the research team.

Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "*What Do I Need to Know Before Being in a Research Study?*" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights or complaints about the research, you

can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463.
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

Signature of Person Obtaining Consent_____Date_____

Authorized Study Personnel
Principal
* Vose, Julie
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degree: M.D.

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Participating Personnel

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