IRB NUMBER: 206519061814

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
MARCELLA NEIHOFF SCHOOL OF NURSING

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Safety, feasibility and efficacy of vitamin D supplementation in women with metastatic breast cancer (SAFE-D)

THE APPROVAL FOR THIS PROJECT EXPIRES ON 06/18/2015.

Participant Information

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

PURPOSE OF RESEARCH: You are being asked to participate in this study because you are a women undergoing treatment for metastatic breast cancer. Many women who have received breast cancer treatments have low levels of vitamin D.

The purpose of this study is two-fold. First, we will determine the safety and effectiveness of treating low blood vitamin D levels in women who have advanced breast cancer. Several studies have shown that increasing serum levels of vitamin D may alleviate some of the joint and muscle pains resulting from breast cancer therapy, but these have been done mainly in women with earlier stage disease and they primarily focus on pain. There is also evidence in patients without breast cancer to suggest that raising levels of serum vitamin D may improve mood and decrease inflammation. Therefore, we are specifically interested in assessing the effects of 8 weeks of high dose vitamin D supplementation on raising vitamin D levels in your blood and measuring whether or not supplementation can improve your symptoms and not interfere with your current breast cancer treatments. This dose you will receive is what is currently recommended for treating low levels of serum vitamin D. You will be asked to provide blood samples before starting on vitamin D to make sure you are eligible to participate in the intervention. If you are eligible and do participate, we will ask you to complete the questionnaires at baseline, half way through the study and then again after you have completed 8 weeks of supplementation. At the end of the study, you will also be asked to provide blood samples and to complete a body scan to assess your body composition.

The second purpose of this study is to examine the occurrence of symptoms and to gauge quality of life in a broader group of women with advanced breast cancer. Therefore, if your serum levels of vitamin D are normal, you will not need the vitamin D supplementation; however, you can still participate in this research project by completing questionnaires and study measures.

Approximately 50 people will participate in this research.

WHAT IS INVOLVED IN THE STUDY?

Vitamin D screening:
You will be initially screened for study eligibility at a routine visit with your medical oncologist or with the study staff. You will have your blood drawn in the Cardinal Bernadin Cancer Center Phlebotomy Laboratory to determine serum levels of vitamin D and other relevant laboratory values (e.g., complete metabolic profile).

By agreeing to be in this study, you will also allow the phlebotomist to draw extra blood (~2 tubes or ~2 tablespoons) so the research team can analyze study specific hormones and inflammatory markers in your blood. Based on the results of your vitamin D blood test, you will be able to participate in one of two study groups.

DESCRIPTION AND EXPLANATION OF PROCEDURES:

Group 1: If your serum levels of vitamin D are low and you agree to participate in this study, you will be given 50,000 IUs (one capsule to swallow) of vitamin D each week for 8 weeks to treat your low level of vitamin D. This is the same amount and time that is recommended by The Endocrine Society to treat low serum levels of vitamin D. Bio-Tech Pharmacal, Inc. will be

providing the study supplements. You will be asked to come to Loyola University Medical Center for 2 visits to collect information needed for the study.

At the first visit, you will complete baseline data collection and provided the vitamin D supplement.

Following 8 weeks of vitamin D supplementation, you will be asked to return for your follow up visit. Each visit will last 1 to 2 hours.

At the baseline and follow up visit, you will be asked to:

1) Complete questionnaires that ask you about your symptoms, sleep, mood, overall health, quality of life and factors that potentially impact your vitamin D level (e.g., sun exposure, diet, etc.).

2) Perform non-invasive tests to assess your muscle function and to obtain other body measures like height, weight and body composition

3) At the follow up visit, you will have another blood draw (about 2 tablespoons) for tests that will tell us about your serum levels of vitamin D, other relevant laboratory tests (e.g.,serum calcium), as well as study related hormones and inflammation levels. We will also perform a body composition scan (e.g., DXA) to get information about your bones, muscle mass and percent body fat.

Midway through the study (i.e., approximately 4 weeks after supplementation), you will be asked to complete some symptom questionnaires. This information will be gathered at a time that is convenient for you and should take less than an hour to complete.

To help you remember to take your vitamin D each week, we will contact you by your preferred method (phone, text or email) to remind you to take your vitamin D. You will be instructed to call us at any time with any questions or concerns at 708-216-0344.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. The web site will include a summary of the results. You can search this web site at any time.

Group 2: If your serum levels of vitamin D are normal (i.e., you do not require high dose vitamin D supplementation), you will be invited to complete the study questionnaires and study measures. We will use this information, in conjunction with markers in your blood sample, to characterize symptoms in women with advanced breast cancer and to identify potential areas for future intervention. You will be offered the option to complete the questionnaires over the telephone, via mail or in person at Loyola University Medical Center.

Optional bio-banking: You may optionally agree to allow us to collect and store approximately two tablespoons of blood collected from you during your study visit. This blood will be coded

and paired with coded clinical data for future research purposes. We will ask you to sign a second, separate informed consent document if you agree to bank samples for future research. You do not need to agree to the collection and storage of your blood in order to participate in this study.

RISKS/DISCOMFORTS: There are several risks/discomforts associated with your participation in this study.

Group 1 only: First, it is possible that vitamin D supplementation could interfere with your breast cancer treatments. There is a risk that vitamin D supplementation could lead to increased estrogen production, and higher estrogen levels are associated with increased breast cancer activity.

Second, it will be important that you do not take other vitamin D supplements while in this study other than your 50,000 IUs per week. Published reports suggest that 50,000 IUs per day of vitamin D (note this study is approximately 7,000 IUs per day) can increase vitamin D and cause high calcium levels; a condition known as hypercalcemia. We will be checking your calcium level in your blood before and after you start taking your supplement.

Third, there are potential side-effects of taking vitamin D. The most common side-effects reported include: bone pain, constipation, dry mouth, headache, nausea and vomiting. Since vitamin D can increase serum calcium, there is the potential to develop kidney stones. While you are involved in this study, you will be instructed to get your calcium from dietary sources and limit calcium supplementation to no more than 1,000 mg per day to help minimize the risks of developing a kidney stone. We will be monitoring for side-effects during your study visits and via the phone. If you are unsure if you should participate in this study, you should speak with your healthcare provider first.

Fourth, a DXA scan will be used to measure your body composition. There is radiation associated with a DXA scan, which is about 12 microSieverts. However, this amount is less than the radiation absorbed by a passenger on a transcontinental flight (about 60 microSieverts.)

Groups 1 & 2: You may experience a slight discomfort when the blood is drawn for the laboratory tests.

You may also experience some mild discomfort or anxiety in answering questions of a personal nature about your health and behavior. If you feel uncomfortable at any point answering these questions, you may skip a given question.

While every effort will be made to protect your identity and health information, there is a small risk of loss of confidentiality that information about your health might become known to individuals outside the study. To minimize this risk, we will keep identifying information separate from your data, use identification code numbers on data forms, use locked filing cabinets and storage areas, and use password-protected computer files.

In addition to the risks mentioned above, there may be unknown or unanticipated risks associated with participating in this study.

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The vitamin D intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are currently pregnant, trying to get pregnant or breast feeding.

If you are a woman of childbearing potential, a pregnancy test will be done to make certain that you are not pregnant before beginning the study and prior to the body composition scan.

Women who are able to have children must use an effective method of preventing pregnancy while participating in this study.

In addition, as study medications may remain in the body for a period beyond their administration, you will be asked to continue to employ an effective method of preventing pregnancy for 6 months after you have finished taking the study medication.

BENEFITS: We do not know if you will directly benefit from participating in this study. Through your participation you will provide valuable information on how often low levels of vitamin D occur and what treatment side effects exist for women with advanced breast cancer. If you are eligible and do participate, you could receive an effective treatment to raise your vitamin D level and this may help with treatment-related symptoms, like pain, fatigue and mood. The information we learn may also help others in the future.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project. You can choose to start vitamin D treatment without participating in the research project. You should consult with your health care provider.

FINANCIAL INFORMATION: You will be financially responsible for the cost of all routine laboratory tests, procedures, hospitalizations (if necessary), non-study medications and physicians fees. However, neither you nor your insurance provider will be billed for any procedures that are performed exclusively for this research study. Those procedures that are being performed for research purposes only include study related laboratory testing and a study related DXA. The vitamin D supplementation will be provided for free.

If you choose to participate in this study, beyond the vitamin D screening, you will be compensated for your time. Participants who receive the high dose vitamin D supplementation will receive a maximum of $50 for participation, including $20 for completion of the baseline visit and $30 for completing the follow-up visit. Participants in group 2, will receive $20 for the completion of the baseline study visit activities. Parking will be paid for those who return to LUMC for study-related visits.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Loyola

University Health System or Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

IN THE EVENT OF AN EMERGENCY: In the case of a life-threatening emergency, regardless of whether or not it is related to your participation in this study, please call 911 or proceed to the nearest Emergency Room.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and any medical conditions from you, your Loyola University Medical Center (LUMC) medical records or your medical oncologist. The information will be collected by Dr. Patricia Sheean and her research team, the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University Chicago; Loyola University Medical Center, data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

In this way, we will learn more about vitamin D and its relationship to symptom management.

The information we will collect and send includes:

X____ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number, Social Security Number)

X____ BLOOD SAMPLES

X_____SURVEYS

X_____BODY COMPOSITION AND PHYSICAL MEASURES

X_____INFORMATION FROM YOUR MEDICAL RECORD ABOUT YOUR BREAST CANCER, YOUR TREATMENTS AND YOUR SYMPTOMS.

We will collect and provide this information about you for as long as you are in the study. .

Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to LUMC and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop. However, information already used and disclosed prior to the time of your withdrawal from this study may continue to be used and disclosed by LUC and/or LUMC.

For your safety, we may ask that you return to clinic one more time for laboratory tests if the supplement is discontinued by the study physician. We will also ask that you return any unused study medication. If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Patricia Sheean, PhD, RD or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, may terminate the study at any time with or without your consent.

Your study doctor may choose to take you out of the study because of unexpected or serious side effects, treatment non-compliance, or because you are not taking the medication as you were instructed. You may also be removed from the study if your study doctor feels that you are not benefiting from the study treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-0344 .

_____Date:____/_____/____
Signature

Patricia Sheean, the principal investigator for this study, or her associate will be available to answer any questions you may have. Dr. Sheean can be reached at: 708-216-0344.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or Elaine Fluder, MSN, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/____
Signature: Witness

PROJECT TITLE: Safety, feasibility and efficacy of vitamin D supplementation in women with metastatic breast cancer

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Safety, feasibility and efficacy of vitamin D supplementation in women with metastatic breast cancer", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Patricia Sheean, PhD, RD
Loyola University Medical Center
2160 South First Avenue
Maywood, Il