

Kansas City Clinical Oncology Program

(PREDICT)

A Multi-Center Study in Patients Undergoing Anthracycline-Based Chemotherapy to Assess the Effectiveness of Using Biomarkers to Detect and Identify Cardiotoxicity and Describe Treatment

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. You are being asked to take part in this study because you will be receiving anthracycline-based chemotherapy, which may cause heart damage. Anthracyclines are a group of chemotherapy drugs commonly used to treat a variety of cancers and have been associated with a potential to cause heart damage.

WHY IS THIS STUDY BEING DONE?

The goal of this clinical research study is to learn if certain biomarker testing on blood samples can help to detect heart damage that may occur during chemotherapy. Biomarkers are chemical traits found in the blood. The biomarkers being used in this study are the BNP and Troponin I. Both will test heart function. High levels of these markers may be linked with heart problems such as heart damage.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 830 patients will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Screening Visit

Before you can take part in this study, you will have "screening tests." These tests will help your study doctor decide if you are eligible to take part in this study. These tests would likely be performed even if you weren't taking part in this trial. You may not need these tests repeated if you have had them in the last few months. Your doctor will let you know if the tests need to be repeated. The following tests and procedures will be performed before taking part in this trial:

- Your complete medical history will be recorded.
- You will have a physical exam, including measurement of your vital signs (blood pressure, heart rate, and breathing rate), height and weight, and your body mass index (BMI). The BMI is a relationship between weight and height that is associated with body fat and health risk.
- You will complete a questionnaire about any symptoms you may be experiencing. It should take about 5-10 minutes to complete.
- You will have an echocardiogram (a sound wave test of the heart) or MUGA to check your heart function.
- You will have an electrocardiogram (EKG), [a test to measure the electrical activity of the heart].
- Blood (about 1 teaspoons) will be drawn for biomarker (A specific physical or chemical trait used to measure or indicate the effects or progress of a disease, illness, or condition) testing. These biomarker test include the following:

- A BNP and Troponin I, these blood tests look at the function of your heart
- You will have (about 2 teaspoons) of blood drawn for routine tests. You may not need these tests repeated if you have had them in the last few months. Your doctor will let you know if the tests need to be repeated. These routine tests include the following:
 - A CBC, this test looks at the different parts of the blood
 - A chemistry panel, this test checks the electrolytes (sodium potassium, etc.) and organ function in the body
 - A thyroid panel, this test looks at the function of the thyroid gland (the thyroid gland produces hormones that help to regulate different functions of the body) and;
 - A lipid panel, this test looks at your cholesterol (the amount of fat in your blood) level

Study Visits

If you are found to be eligible to take part in this study, you will have study tests and procedures performed on the same days as your scheduled chemotherapy treatment. These study visits will occur about every 3-4 weeks apart. You and your doctor will work together to determine the type of chemotherapy and the exact number of cycles of chemotherapy you will have.

At each chemotherapy visit, before you receive your chemotherapy the following tests and procedures will be performed:

- You will have a physical exam, including measurement of vital signs.
- Blood (about 2 teaspoons) will be drawn for routine tests.
- Additional blood (about 1 teaspoon) will be drawn for biomarker testing.

At any time during the study, if your doctor thinks it is medically necessary, you may have any of the routine tests, echocardiogram, MUGA, or EKG repeated.

At the beginning of every 3rd cycle of chemotherapy, in addition to the above test and procedures you will be asked to complete the following:

- You will complete a symptom questionnaire.

At about 6 months (follow-up visit) and at about 12 months (end of study visit) from the start of your chemotherapy, the following tests and procedures will be performed:

- You will complete the symptom questionnaire.
- You will have a physical exam, including measurement of vital signs.
- Blood (about 2 teaspoons) will be drawn for routine tests.
- Additional blood (about 1 teaspoon) will be drawn for biomarker testing.
- You will have an EKG.
- You will have an echocardiogram or MUGA.

At any time during the study, if your doctor thinks it is necessary, you may have any of the routine tests, echocardiogram, MUGA, or EKG repeated.

If you stop receiving chemotherapy during your participation in this study, you will still be asked to complete the above tests and procedures at 6 and 12 months from the start of your chemotherapy. Other tests and procedures scheduled during the study may be waived because

you are no longer receiving chemotherapy treatment. Your study doctor and the research staff will go over this information with you should this occur.

Research Test Results

The results of your biomarker tests will not be part of your medical record and will not be routinely shared with you or your oncologist unless the results show a heart problem. In that case, the study doctor will contact you right away to advise you about what to do next (for example, coming in to the clinic). If you have any abnormal biomarkers you will be referred to a consulting cardiologist (heart doctor) within one week to discuss treatment. The cardiologist will advise you on what to do next regarding your heart problem.

HOW LONG WILL I BE IN THE STUDY?

Your study participation will last about 12 months from date of your first chemotherapy treatment. You will have a follow up visit at about 6 months from the date of your chemotherapy and an end of study visit at about 12 months from the date of your first chemotherapy treatment. This will end your participation in the study.

CAN I STOP BEING IN THE STUDY?

Yes. You can stop taking part in this study at anytime. If you decide to stop taking part in this study, we encourage you to talk with your study doctor first.

It is important to tell your study doctor if you are thinking about stopping the study so that any risks from the biomarker testing can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping the study is to give your doctor a chance to discuss any follow up care or testing that could be helpful to you.

Your study doctor may decide to take you off the study at anytime without your permission if he feels it is in your best interest; if you do not follow the study rules; or if the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

While on this study, you are at risk for the side effects listed in this form. You should discuss these with the study doctor or your regular doctor. The known side effects are listed in this form, but they will vary from person to person.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, you are encouraged to contact your study doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. The biomarker testing used in this study may help to detect serious heart problems early. Future patients may benefit from what is learned. There may be no benefits for you in this study.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to take part in the study.

If you choose not to participate in the study, you will receive usual medical care, including treatment for pain and other symptoms of your cancer, if you decide not to participate. Please talk to your regular doctor about other options. Other options may include:

- Taking part in another research study
- Getting treatment or care for your cancer without being in a study
- Getting no treatment at all

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- MD Anderson Community Clinical Oncology Research Base
- The National Cancer Institute (NCI) and or,
- Other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You and/or your health plan/ insurance company will need to pay for some or 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 MD Anderson CCOP Research Base is supplying biomarker testing equipment and supplies to perform the biomarker testing at no cost to you. You and/or your insurance provider will be responsible for the costs of the routine tests performed and cardiology consultations due to abnormal testing during this study (routine blood tests, EKGs, and echocardiograms).

The MD Anderson CCOP Research Base will supply the biomarker testing and supplies for the testing at no charge while you take part in this study. The MD Anderson CCOP Research Base does not cover the cost of getting the biomarker testing ready and performing the test, so you or your insurance company may have to pay for this.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the biomarker testing equipment and supplies to the MD Anderson CCOP Research Base for some reason. If this would occur, other possible options are:

- You might be able to get the biomarker testing directly from the manufacturer but you or your insurance company may have to pay for it.

- If there is no biomarker testing available at all, no one will be able to get more testing and the study would close.

If a problem with getting biomarkers tested occurs, your study doctor will talk to you about these options.

You will not be paid for taking part in this study.

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 Web site.

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.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, _____ [*investigator's name(s)*], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ [*telephone number*].

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher _____ at _____ (TELEPHONE NUMBER).

For questions about your rights as a research participant, contact the Kansas City Clinical Oncology Program Institutional Review Board (which is a group of people who review the research to protect your rights) at 913-948-5588.

TAKING PART IN ADDITIONAL STUDIES

This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies

if you want to. You can still be a part of the main study even if you say 'no' to taking part in any of these additional studies.

About Using Blood for Research

In addition to routine tests and heart biomarkers we would like to draw additional blood (about 1 teaspoon) for future research. We would only draw blood once for this future research. The one time blood draw will be drawn at the beginning of the study. If you agree, this blood will be kept and stored in a research blood bank at Vanderbilt University Medical Center-Cardiology Core Lab in Nashville, Tennessee for use in future research related to cancer and other diseases.

The research that may be done with your blood is not intended to specifically help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your blood will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us draw and store additional blood for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your blood can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your blood (this is withdrawing your consent). Then any blood that remains will no longer be used for research. However, if any of your blood has already been released for research before you withdraw your consent, M. D. Anderson will not be able to destroy the blood that was released.

In the future, people who do research may need to know more about your health. While MD Anderson may give reports about your health, it will not give your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes blood is used for genetic research (about diseases that are passed on in families). Even if your blood is used for this kind of research, the results will not be put in your health records.

Your blood will be used only for research and will not be sold. The research done with your blood may help to develop new products in the future.

Benefits

The benefits of research using blood include learning more about what causes heart and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

No matter what you decide to do, it will not affect your care.

1. I give my permission for additional blood (about 1 teaspoon) to be collected.

Yes No

If you answered 'no' to question one skip questions 2, 3, and 4, and move to the next section titled, "Where Can I Get More Information".

2. My blood may be kept for use in research to learn about, prevent, or treat cancer.

Yes No

3. My blood may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No

4. Someone may contact me in the future to ask me to take part in more research.

Yes No

WHERE CAN I GET MORE INFORMATION?

You may call the NCI's **Cancer Information Service** at:
1 800 4 CANCER (1 800 422 6237) or **TTY: 1 800 332 8615**

Visit the NCI Web site:

- <http://www.cancer.gov/>

You will get a copy of this form. If you want more information about this study, ask your study doctor. You may also request a copy of the protocol (full study plan).

SIGNATURE

I have been given a copy of all 7 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant _____ Date _____

Witness _____ Date _____

Approval Date: 8/12/11 to 6/22/12
Assurance #: FWA00003582