Informed Consent Form

Winship2656-14: Comparison of Quality of Bone Marrow Biopsy and Patient Convenience and Pain Control by a Battery Powered Drill Versus Conventional Methods in Patients with Plasma Cell Disorders

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You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Winship2656-14: Comparison of quality of bone marrow biopsy and patient convenience and pain control by a battery powered drill versus conventional methods in patients with plasma cell disorders

Principal Investigator: Ajay K. Nooka, MD MPH

Sponsor: Emory University

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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 may search this Web site at any time.

What is the purpose of this study?

The study will enroll patients with multiple myeloma (Blood Cell disorder) undergoing the bone marrow biopsy procedure. This research study is evaluating the effectiveness and patient convenience of a Food and Drug Administration (FDA)-approved battery powered Bone Marrow Biopsy System (power drill) versus the manual Jamshidi bone marrow biopsy needle. Both these methods are used as the standard of care procedures at Emory University. Patients' choice of instrument is used for the procedure. The study will access the efficacy of the two instruments in obtaining a quality of sample and evaluating the resulting pain.

Approximately 100 patients will be enrolled in this study at Winship Cancer Institute of Emory University.

Procedures
You have been asked by your doctor to participate in this study as one of the subjects who will be biopsied with the power drill or the Jamshidi bone marrow biopsy needle. If you agree to take part in this study by signing this Subject Informed Consent Form, you agree to permit the exam procedures.

The study team is available to address any specific questions you may have. You will be randomized to undergo the procedure using the power drill arm or the Jamshidi bone marrow biopsy needle.

Advantages and disadvantages of each procedure
Manual procedure using Jamshidi needle had been the standard method of obtaining bone marrow biopsies for decades. Since it is a manual physical process to drill the bone by repeated hand movements, the comfort to the patient and the quality of the specimen are dependent on the skill of the operator. Some studies had demonstrated that using a power drill resulted in significantly shorter time of the procedure and the sampling was superior in quality, while other studies showed both methods produced similar results. The studies reported that pain during the procedure is lower with the powered drill among patients that receive local anesthesia, but no conclusive studies exist for patients undergoing a bone marrow biopsy with conscious sedation.

Anesthesia:
If you decide to participate in this trial, you will receive conscious sedation. The questions that are being addressed by this study include pain assessment and the patient comfort by the visual analog scale. To have uniformity in pain assessment, all the patients will receive conscious sedation administered by approved personnel that are a part of the study.

Randomization
All the study participants are randomized by using a shuffling card method. 100 cards with procedure names (50 with power drill and 50 with Jamshidi needle) printed on them are shuffled and you will be asked to pick one card from the deck determining your procedural group assignment. Selected cards will be discarded to assist with even procedural group randomization.

Questionnaires
You will be asked to fill out the VAS pain questionnaire before the start of the procedure and 30 minutes after the procedure and on days 1, 3, and 7. You will be given a pain scale to score the intensity of the pain. You will be asked to return to Winship Cancer Institute for a follow-up scheduled visit to discuss the results of the bone marrow biopsy return the VAS pain scale questionnaires.

If you are unable to attend the scheduled follow-up visit, return the VAS pain scale questionnaires using the return stamped envelope provided to you on the day of the procedure.

What are the possible risks and discomforts?
There may be side effects from the study procedures that are not known at this time, but these will not exceed the standard risk associated with the bone marrow biopsy procedure. You are only asked to take part in this study if you are scheduled to undergo the bone marrow biopsy procedure.

This study will not include pregnant women due to risks.

The most common risks and discomforts expected in this study are:
The risks associated with a biopsy are soreness and discomfort. You may receive an injection of anesthesia (a medication that causes numbness) in the area where the biopsy will be taken. You may feel a stinging sensation when the biopsy needle pierces the bone or the tumor. Minor bleeding is relatively common.

The less common risks and discomforts expected in this study are:
The time you spend receiving the standard medical tests associated with your cancer for this research may affect your time at work.

Rare but possible risks include:
Serious bleeding and infection are rare. Tell your doctor immediately if the bleeding is heavy or lasts a long time. To prevent bleeding, your doctor may ask you to stop taking certain medications that interfere with blood clotting.

The biopsy does not increase the chance that your cancer will spread.

Risks from sedation during biopsy
Sedation may slow your breathing, and the nurse may need to give you oxygen to help you breathe.

Your blood pressure may be affected, and you may get intravenous fluids to stabilize your blood pressure.

Because sedation effects may linger, you may have a headache, nausea, and feel sleepy for several hours.

Some people have a brief period of amnesia (not remembering what happened) after receiving conscious sedation.

Will I benefit directly from the study?
You will not be benefitted directly by participating in this study. This study is designed to learn more about bone marrow biopsy techniques used in multiple myeloma patients. The study results may be used to help others in the future.

Who owns my study information and samples?
You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that was already collected may be still be used for this study.

Compensation
You will not be offered compensation for being in this study.

How will you protect my private information that you collect in this study?
Emory will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Ajay Nooka at telephone number [redacted] You should also let any health care provider who treats you know that you are in a research study.

Costs

The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study.

You will have to pay for the items or services that are part of this study. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that are part of this study. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance

companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. 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). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:
- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Food and Drug Administration
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Ajay Nooka, MD
Winship Cancer Institute, Emory University
1365-C Clifton Road NE
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure

that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Dr. Ajay Nooka at [redacted]
- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or [redacted]
- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Please print your name and sign below if you agree to be in this study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

_____
Printed Name of Subject

_____ _____ ____:____ am / pm
Signature of Subject Date Time (please circle)

_____
Printed Name of Person Obtaining Consent

_____ _____ ____:____ am / pm
Signature of Person Obtaining Consent Date Time (please circle)