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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 01/09/2023

Protocol Number: 2014P-000226

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
01/08/2024
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A cross-sectional study to determine whether cortical bone properties can identify women at risk of fragility fractures
PRINCIPAL INVESTIGATOR: Tamara Rozental, M.D.
PROTOCOL NUMBER: 2014P-000226

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Tamara Rozental, M.D., without funding support. BIDMC, Dr. Rozental, and Dr. Brandon Earp have no additional interests in this research project. Co-investigator Mary Bouxsein, Ph.D., is an unpaid member of the scientific advisory board of Active Life Scientific, the company that makes the Osteoprobe device.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Tamara Rozental, M.D., at [617] 667-3940. If you are a Brigham and Women's Hospital participant, you may also contact Brandon Earp, M.D., at (617) 732-8064.

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PURPOSE

The main purpose of this study is to test whether a new device that measures bone strength can identify those who are at risk for fragility fractures of the wrist and hip. This device uses a small amount of force to make very small indentations (dents) in a bone. The depth of the indentations indicates how strong or fragile the bone is.

The medical device involved in this study, The Osteoprobe® (Active Life Scientific, Santa Barbara, CA), is investigational. This means that the study device is still being tested in research studies and is not approved by the Food and Drug Administration [FDA].

STUDY PARTICIPANTS

You have been asked to be in the study because you have had a recent wrist or hip fracture, or because you are a post-menopausal woman, or man older than 50 years, who has never had a fracture as an adult.

Approximately 600 people will take part in this study at Beth Israel Deaconess Medical Center and Brigham and Women's Hospital.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the study doctor will do the following:

    a. Confirm that if you are female, you are postmenopausal;
    b. Confirm with you that you are not allergic to lidocaine, the numbing medicine used;
    c. Check your medical history for any medications or medical conditions that might affect the study results;
    d. Look at your leg, to make sure the device can be used safely and properly;
    e. If you have a wrist or hip fracture, the study doctor will also review your X-ray to confirm the type of injury.

    If you are a patient at Brigham and Women's Hospital, you may be referred to the BIDMC study team by your physician, who is also an investigator for this study. The study team will register you as a BIDMC patient, in order to schedule a visit to the Department of Orthopedics. This visit may include screening procedures above, and if you are eligible and wish to participate, the research

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procedures below. We will not look at your medical records at Brigham and Women's Hospital, but if you were previously seen at BIDMC, we will look at those records.

2. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

   We will ask you to schedule a research visit. At the visit, we will:

   - Ask about your medical history and medications you are taking now or in the past
   - Ask about your lifestyle factors (e.g., smoking history, alcohol use, and physical activity)
   - Draw 2 blood samples (about 1 tablespoon) to measure the levels of vitamin D and hemoglobin A1C.Vitamin D provides information about bone health, and hemoglobin A1C test estimates average blood sugar levels.
   - Schedule a test to measure the bone density of your hip and spine, called a bone mineral density by DXA scan. (If you have had a bone density test of your hip and spine within the past 6 months, we will not repeat it.) This test is usually scheduled for a different day, at your convenience. A DXA scan is a standard test to determine whether someone has osteoporosis, or porous bones. The test is painless and uses X-rays to measure the amount of bone in your hip and spine. We will ask you to lie on a padded table, and an arm-like scanning device will pass over your body. You will need to hold still during the scanning procedure to reduce the possibility of a blurred picture. The procedure will take about 15 minutes.
   - Perform a test to measure the strength of the bone in your shin (front part of leg between the ankle and knee) using the OsteoProbe®. We will ask you to lie down on an exam table. We will clean the skin in the middle of your shin. We will use a needle to inject a small amount of lidocaine under the skin of your shin to numb the area. After the area is numb, we will insert the tip of the OsteoProbe® through the skin into the shin bone. Several small round indentations will be made. The indented areas are very small, about the thickness of a human hair. After the procedure is complete, we will clean the testing area and cover with a Band-Aid. The procedure will take about 15 minutes.

One of the study team members will call you within 24-48 hours after the procedure, to check that there are no side-effects. After the phone call, your participation in the study is over.

You will receive a mailed copy of the results of your bone density scan (DXA test) and the results of your vitamin D and A1C tests from your blood sample.

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The test of your shin bone is being done for research purposes only, and we won't provide those results.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

Risks of the bone indentation test

The probe of the device is inserted through the skin and rests up against the bone in your leg. As measurements are taken, the device will make microscopic indentations into the bone that are approximately 200 micrometers in depth, or about the width of a few human hairs. You may have a bruise (black-and-blue mark) or pain where we perform the bone indentation test. There is also a small risk of feeling lightheaded, fainting, or infection. There may be other risks of the bone indentation test that are unknown at this time.

You may feel some pain when the local anesthetic is given to numb the testing area on your shin bone. Some people (fewer than 1 in 10,000) are allergic to the numbing medication (lidocaine). Rarely, a severe allergic reaction (anaphylaxis) to lidocaine may occur that could be life-threatening. Also, a burning sensation at the spot where the lidocaine is injected may occur. Other risks of lidocaine include: low blood pressure, nausea, and slow and/or irregular heartbeat.

Risks of having blood drawn

The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection at the site of the blood draw.

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Allergic reaction to lidocaine (numbing medication)

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious, and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, tell the study doctor right away.

Risks from DXA scan

This research study may involve exposure to radiation from bone mineral density testing by DXA. This radiation exposure may not be necessary for your medical care and is for research purposes only. This is in addition to the radiation exposure that you will receive as part of standard care. Using the standard way of describing radiation exposure, from participating in this study you will receive a total of 0.025 mSv.

For comparison, the average person in the United States receives a radiation exposure of 0.003 Sv (or 3 mSv) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is about the same amount you would normally receive in less than one week from these natural sources.

One possible effect that could occur at these doses is a slight increase in the risk of cancer. Please be aware that the natural chance of a person getting a fatal cancer during his/her lifetime is about 1 out of 4 (or 25 percent). The increase in the chance of getting a fatal cancer, as a result of the radiation exposure received from this research study, is less than 1 in 25,000 (or much less than 1/100th of a percent). Therefore, the total risk of fatal cancer may be estimated to increase from 25 percent to 25.01 percent. This additional risk is too small to be measured and is generally regarded as insignificant.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information learned from your participation in this study and from your research blood test, BMD by DXA scan, research bone test, and your medical records may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center with protection of

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confidentiality so far as permitted by applicable law. Information resulting from this study and from your research blood test, research bone test, and your medical records may be used for research purposes and may be published; however, you will not be identified by name in such publications.

POSSIBLE BENEFITS

There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you can receive treatment without participating in this research.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center or Brigham and Women's Hospital.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

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You will not be charged for the study visit, blood draw, the lidocaine used to numb your shin, the test to measure your shin bone strength, and all the other tests and procedures that are part of this research study. If the BMD by DXA scan to measure your bone density is scheduled by the study team, you will not pay for it. However, you and your insurance company will be charged for tests, procedures or medications of this study that are considered standard treatment for your medical condition.

CO-PAYMENT/DEDUCTIBLE STATEMENT

You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

PAYMENTS TO YOU:

We will pay you $50 for completing the study visit and bone mineral density by DXA scan.

It may take up to 8 weeks for you to receive payment by check.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

We will give you a voucher (coupon) to pay for your parking at BIDMC for any research-only visits, or if you are scheduled for the DXA test.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

A description of this clinical trial will be available on www.ClinicalTrials.gov as required by U.S. law.

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This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, as well as any new information generated as part of this study) as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

-
- Any external health care providers who provide services to you in connection with this research;
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research (Quest Diagnostics);

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- Your health insurance company;
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research;
- Hospital and Clinical Research Accrediting Agencies

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to **Tamara Rozental, M.D. at 330 Brookline Ave., Boston, MA 02215**. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

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RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).
I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____