Randomized controlled trial assessing transperineal prostate biopsy to reduce infection complications

NCT04843566

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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
WEILL CORNELL MEDICINE

SUBJECT INFORMATION AND FIRST-STAGE INFORMED CONSENT FORM

Protocol Title: Randomized controlled trial assessing transperineal prostate biopsy to reduce infection complications
BRANY ID #: 18-02-365
Sponsor: Weill Cornell Medicine

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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in a research study because you have an indication to undergo a prostate biopsy as recommended by your physician.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the comparative effectiveness and tolerability of outpatient transrectal prostate biopsy versus transperineal prostate biopsy, both MRI-targeted.
Consent Process	Typically when participating in a research study, all the information is provided upfront in one consent form. Instead, this is a two-step consent process that gives only information needed at the time. This is the first stage of the consent process, where you are consenting to participate in a research study that allows us to track and compare prostate biopsy outcomes.
Experimental/ Investigational	You will not receive any experimental drugs or procedures as part of this study. You will be randomly assigned to receive one of two comparable outpatient prostate biopsy procedures that are currently available. If you are selected to receive the transrectal biopsy, there will be no further consent discussions related to this research and you will receive medical treatment as usual. You will also fill out research questionnaires, as described below. If you are selected to receive the transperineal biopsy, we will talk to you about it then. You will decide at that point in time if you want to

	have the transperineal biopsy. You do not have to have it if you do not want to. If you are selected for the new approach and decide to have it, you will sign another consent form at that time. This second consent will discuss the risks and benefits and other information specific to the transperineal approach. You will never receive any treatment without us telling you about it first. You will always have the chance to say "Yes" or "No" to any treatment. After the biopsy, you will fill out a questionnaire that asks about urinary and sexual function, and complications following the procedure. Your health information will be de-identified and stored by the hospital.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation in the study is expected to last up to 7 days. During that time, you will have 2 study visits: a screening visit and day of biopsy visit. You will also complete a questionnaire immediately after your biopsy and 7 days after biopsy.
Procedures	The main procedures in the study include: • *Transrectal prostate biopsy; or* • *Transperineal biopsy* • *Questionnaires* The study doctor will explain which procedures are being done for research, and which would be done as part of your standard care even if you don't participate.
Risks	Taking part in this research may expose you to risks (side effects). There are risks from study procedures. Side effects may range from being mild to life-threatening and may go away with treatment or be permanent. The common/main risks of the biopsy include: • Blood in urine, stool, and/or semen • Infection • Discomfort • Urinary retention • Bleeding due to accidental injury The study doctor will explain the risks of this research to you before you decide about participation.

Benefit	There is no guarantee that you will benefit as a result of your participation in this study, however the study results may help people in the future.
Alternative(s) to Study Participation	You do not have to participate in this study to receive treatment for your condition. The study doctor will discuss study alternatives with you and their risks and benefits.
Costs	Participation may result in costs to you, as applicable: You or your insurance company will be responsible for the cost of the biopsy performed within the study, as it falls within standard of care.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

You are being asked to be a participant in a research study because you have an indication to undergo a prostate biopsy as recommended by your physician. This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician.

You can choose to not participate in this study. If you choose to participate in this research study, you can choose to withdraw from it at any time. If you decide not to participate or you later choose to withdraw from participation, your decision will not affect your present or future medical care and there will be no penalty or loss of benefits to which you are otherwise entitled.

If you agree to take part in this research study, you will be asked to sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

Weill Cornell Medicine, the sponsor of this study, is providing funds on a per subject basis for conducting this research study.

PURPOSE OF THE STUDY

Doctors know a lot about the performing prostate biopsies. However, we are always trying to learn more and improve our skills for our patients' benefit. We would like to try and make prostate biopsies safer, with less side effects for the patient and look for a better way to find cancer.

In this study, we will monitor if there are problems after a participant's standard of care prostate biopsy. We will also document the results of the biopsy and patient-reported quality of life.

We are asking those individuals who join the study if we can offer them an alternative and comparable approach to prostate biopsy. Those who agree to participate may hear about this approach and decide whether they are interested. None of the changes we are considering have significant risks or involve large changes to the prostate biopsy.

NUMBER OF SUBJECTS AND LENGTH OF STUDY
About 1,702 subjects are expected to participate in this study at 12 research sites in the United States.
Your participation in this study is expected to last 7 days.

STUDY PROCEDURES

If you take part in this study, you agree to have your routinely collected clinical data used for research purposes. Questionnaires will be also administered immediately after your biopsy and during a 7 day follow up visit to assess symptoms after your procedure.

Please advise your study doctor or their team of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the study doctor or their team.

As part of this study, you may be will be randomly assigned to receive one of two comparable outpatient prostate biopsy procedures that are currently available. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the your study doctor will choose what group you will be in. You will have a 1 in 2 chance of being placed in any group.

If you are selected to hear about the transperineal approach, we will talk to you about it then. You will decide at that point in time if you want to have it. You do not have to have it if you do not want to. If you are selected for the new approach and decide to have it, you will sign another consent form at that time.

This second consent will discuss the risks and benefits and other information specific to the alternative approach. You will never receive any treatment without us telling you about it first. You will always have the chance to say "Yes" or "No" to any treatment.

If you are selected for the transrectal approach, there will be no further discussions related to this research and your active participation on this study will end after you complete the post-biopsy questionnaires.

Clinically Relevant Results
If results of study procedures (e.g. blood tests, imaging scans) provide clinical information that may be important to your health care, you will be told about those results.

PARTICIPANT RESPONSIBILITIES
As a participant in this study, you will have certain responsibilities, including the following:

- Attend all study visits and, if needed, reschedule appointments as soon as possible
- Follow the instructions of the study team
- Check with the study doctor before taking any new medicines (including prescription, over-the-counter, vitamins and herbal supplements)
- Tell the study doctor or study staff any time you do not feel well or if you have any side effects

RISKS AND DISCOMFORTS
For research studies involving prostate biopsy, there may be risks. These risks will be discussed with you by the study doctor and/or your regular doctor.
Risks and side effects related to the prostate biopsy we are studying include:

Likely
- Blood in semen (92.6%)
- Blood in urine (65.8%)
- Discomfort or pain during or following the procedure (43.6%)
- Blood in stool (36.8%)

Possible
- Infection – may range from urinary tract infection to sepsis, a potentially life-threatening condition caused by the body's response to an infection (5% for transrectal; 0.1% for transperineal)
- Urinary retention (1%)
- Bleeding due to accidental injury (1%)

There may also be side effects, other than listed above that we cannot predict. Other drugs may be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the prostate biopsy, but in some cases side effects can be serious, long lasting or permanent.

NEW INFORMATION
You will be notified in a timely manner if important new findings become known that may affect your willingness to continue in the study.

For example, if we learn about new risks, we will share that information with you. If we think you need to know quickly, the study doctor or their staff may call you. If we do not think you need to know quickly, we will tell you at your next visit. If you still want to participate, we may ask you to sign a new consent form.

BENEFITS
There is no guarantee that your condition will improve as a result of your participation in this study. It may stay the same or worsen. However, the information learned from this study may help other people with this disease in the future.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to participate in this study to receive treatment for your condition. Instead of being in this study, you have these options:
- You may choose not to participate in this study.
- You may choose a standard transrectal MRI-guided biopsy without being in the study.
- You may choose a standard transperineal MRI-guided biopsy without being in the study.

The study doctor will discuss study alternatives with you and their risks and benefits.

COSTS OF PARTICIPATION
Participation may result in costs to you, as applicable:

You or your insurance company will be responsible for the cost of the biopsy performed within the study, as it falls within standard of care.

The costs of medications and the administration of these medications that you receive during this study will be charged to you or your insurance provider.

The physical examinations, standard laboratory tests, and diagnostic procedures such as the MRI scans involved in this study are considered part of the standard care for patients with your disease. The costs associated with each test will be charged to you or your insurance provider in the same manner as if you were not part of this research study. Therefore, you or your insurance provider will need to assume responsibility for these costs. You will be billed for all costs or co-payments that are not paid by your insurance provider.

Taking part in this study may lead to added costs for you or your insurance company. Please ask about any expected added costs or potential insurance problems. You may wish to consult with your insurance company in advance about whether insurance will pay for these costs.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

REIMBURSEMENT
You will not be paid for participation in this study.

You will not receive reimbursement or compensation for out-of-pocket study visit expenses such as travel, parking, and meals.

COMPENSATION FOR INJURY
We are obligated to inform you about WCM's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCM or NewYork-Presbyterian Hospital. For medical emergencies, call 911. No other compensation will be offered by Weill Cornell Medicine or the sponsor or Biomedical Research Alliance of New York for things such as lost wages, disability, or discomfort as part of this study.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY
To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot

be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

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 can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products

resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Collection of Identifiable Private Information or Identifiable Biospecimens:

- Identifiers might be removed from your identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or the New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

CoC (CERTIFICATE OF CONFIDENTIALITY)

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have

consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by Weill Cornell Medicine which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as research data in your medical record.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor as soon as possible.

If you choose to withdraw from the study early, it is important to know that data collected up until the time you withdraw will remain part of the study database and cannot be removed, and will still be used and given to others.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA or other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

CONTACT FOR ADDITIONAL RESEARCH

Please indicate whether you will allow the investigator to provide your contact info to members of the research team at Memorial Sloan Kettering (MSK) to tell you about an opportunity for additional research. Please check the box below that describes your wishes:

☐ YES, the investigator may provide my contact information to members of the research team at MSK.

☐ NO, the investigator may not provide my contact information to MSK.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Jim C. Hu at (646) 962-9600.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT

By signing this form, I confirm the following:

- I have read all of this consent form and know what is involved in the study.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed consent form to keep.
- I do not give up any legal rights by signing this form.

I voluntarily agree to participate in this study.

Subject: Name (Print)	Signature	Date

Person Obtaining Consent: Name (Print)	Signature	Date