Official Title	BURN Study: Buffered Lidocaine in Reducing Pain From Prostate Biopsy
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E-Consent Email

Subject Line: "RESPONSE REQUIRED: UW Consent Form for BURN study"
Sent From: Alex Zhu (azhu5@uw.edu)
Body:

Department of Urology
Since 1956

Hello Mr./Mrs. XYZ,

Thank you for spending the time to chat with me about the **BURN** study.

As a brief review, our research study tries to determine how to make prostate biopsies **more comfortable** and **less painful** for patients. We are doing this by investigating the best type of local anesthetic to give to patients during the procedure.

If you are interested in participating, please:

1) Complete the electronic consent
2) Complete the survey questions **(21 questions, takes <5 minutes to complete)**

Thank you for participating in our research! **You** are contributing to science. **You** are improving our knowledge of how to make prostate biopsies more comfortable for patients. **You** are helping patients around the world who are undergoing prostate biopsies.

Please click on this link to complete the consent form and survey questions

If you have any questions about the study, please contact me at:
Alex Zhu, DO
Acting Clinical Instructor, Department of Urology University of Washington
Cell: (949 633 6048)
Email: azhu5@uw.edu

INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Buffered Lidocaine in Reducing Pain of Prostate Biopsy

Co-Principal Investigator:

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Acting Instructor

Urologic Oncology Fellow

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Key Information about this study and what you will be asked to do.

What is the purpose of this study?

We are conducting this study to find a better way to perform prostate biopsies, in order to make them more comfortable for our patients.

Why am I being contacted for this study?

You are being asked to participate because you are scheduled for an upcoming prostate biopsy.

What is the rationale of the study?

Men often find prostate biopsies painful. Typically, urologists perform these biopsies while the patient is awake, using a local anesthetic called Lidocaine. However, Lidocaine is acidic, which is thought to cause a burning sensation or pain when injected, similar to the discomfort experienced during some dental procedures.

To minimize this burning or pain, many doctors are now using a local anesthetic called "Buffered Lidocaine." This is a solution that combines Lidocaine with a medication called Sodium Bicarbonate. The Sodium

Bicarbonate reduces the acidity of the Lidocaine, potentially easing the burning or pain that patients have during injection of the local anesthetic.

While Buffered Lidocaine is commonly used in other medical procedures, its effectiveness in prostate biopsies has not been studied yet. Thus, we would like to see if **Buffered Lidocaine can reduce the burning and/or pain that men have during prostate biopsies**, and see if this solution can make prostate biopsies more comfortable for men.

What additional work do I have to do as part of this study?

By participating in the study, you will have to complete **three** surveys. These surveys will ask about your pain and anxiety related to the prostate biopsy procedure. Each of these surveys takes **<5 minutes** to complete.

The surveys will be completed:

- First survey: At least 2 days before your biopsy (emailed + completed online)
- Second survey: During your prostate biopsy (completed in-person, on the day of your biopsy)
- Third survey: One day after your prostate biopsy (emailed + completed online)

Participation in the study will **NOT** require any additional doctors visits or travel. Participation in the study will **NOT** lead to additional costs to you, or your insurance company.

What will happen to me during the study?

Prior to your biopsy:

You will complete a survey asking about your baseline anxiety and pain.

On the day of biopsy:

During your prostate biopsy, you will be randomly selected to receive either Buffered Lidocaine or regular Lidocaine as your local anesthetic. Neither you nor your doctor will know what type of local anesthetic you receive. Following injection of the local anesthetic, your doctor will complete the prostate biopsy in the standard fashion. You will be asked to complete a survey rating the pain associated with the prostate biopsy procedure.

On the day following the biopsy:

You will complete a survey asking about the pain and discomfort of the prostate biopsy procedure.

Do I have to participate in the study?

Being in this study is completely **voluntary**. This means that you can refuse to sign up. It also means that if you do sign up, you can decide to stop being in the study at any time without penalty. Refusing to sign up or withdrawing from the study will **NOT** affect your relationship with your healthcare provider, nor will it affect the treatment you receive.

Will I be compensated for being in the study?

No financial payment will be made to patients for their participation in the study.

Reasons you might say "yes" to being in the study.	Reasons you might say "no" to being in the study.
Benefits to you • If you are randomly selected to receive Buffered Lidocaine, you may potentially have a more comfortable biopsy procedure (with less burning and/or pain) • The knowledge gained from this study will allow your urologist to understand the best type of local anesthetic to use for prostate biopsies. Thus, if you are to have any prostate biopsies in the future, your urologist will be able to choose the best type of medication to improve the comfort and tolerability of any future prostate biopsies you may receive **Benefits to society** • The knowledge gained from this study may help improve the comfort and tolerability of prostate biopsies for men across the world	**Downsides/Risks to you** • Participation in the study requires that you take the time to fill out three surveys (<5 minutes each). You may also be contacted via telephone or email in regards to the study. • There is a possibility that Buffered Lidocaine may be associated with the same, or worse amount of pain, as compared to regular Lidocaine • There is a rare chance that you may develop an adverse reaction (allergic reaction, bleeding, bruising) to the Buffered Lidocaine solution. However, studies of thousands of patients using Buffered Lidocaine in other specialties have not shown any adverse events besides a few (<5) cases of bruising at the local anesthetic injection site

	• This is the first study evaluating Buffered Lidocaine for prostate biopsies, thus there is a chance that unforseen risks may occur.

Do I have options outside of this study?

If you choose not to participate in the research, you will receive a prostate biopsy in the standard fashion, using regular Lidocaine.

What can you do if you want more information?

Read more about this study. The next pages of this form give you more information about the study

Talk to the study team. We are here to help you understand the study. Please ask us any questions you have, even about things that are not in this document. It is our responsibility to give you the information you need to make a decision and give you time to think about whether or not you want to sign up.

Talk to someone else. You may want to discuss your decision about whether to sign up with your family, friends, your regular doctor, or someone else. You can show them this document to help them talk about the study with you.

Talk to someone about your rights as a subject. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division at hsdinfo@uw.edu or 206.543.0098.

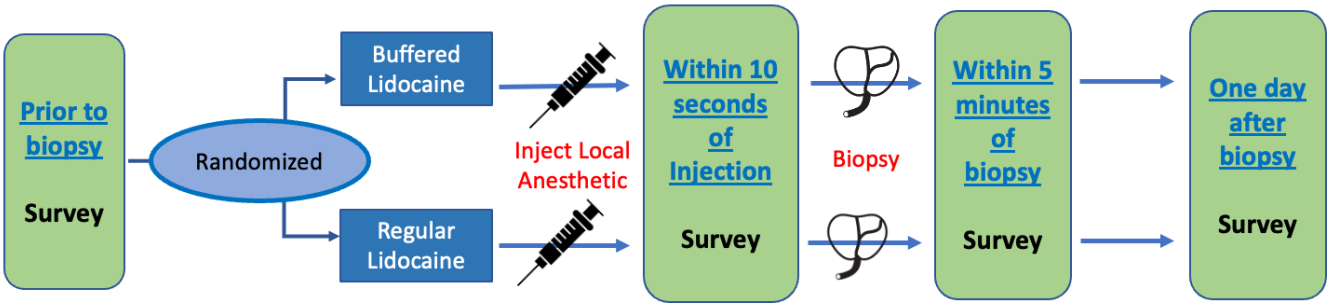
Additional information about research procedures.

Additional Information about Buffered Lidocaine

Buffered lidocaine is composed of Lidocaine and Sodium Bicarbonate. The FDA (US Food and Drug Administration) has approved the use of both Lidocaine and Sodium Bicarbonate to be injected under the skin (subcutaneously) or intradermally (within the skin). However, the combination of the two (Buffered Lidocaine) is not specified in the labeling for these drug products. Thus, Buffered Lidocaine does not have FDA approval for use as a local anesthetic.

In spite of this, many doctors from other specialties routinely use Buffered Lidocaine for their anesthetic procedures. Many scientific studies have been published about the use of Buffered Lidocaine within these other medical specialties (ex. dental procedures, dermatology, pediatrics, emergency medicine, etc). These studies have shown that Buffered Lidocaine is safe and reduces pain of the local anesthetic.

Diagram of the Study



How will we protect the information you provide?

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team. When we publish the results of this study, we will not use your name. If we learn you intend to harm yourself or others, we must report that to the appropriate authorities. Information about the study and your study results may be placed in your UW medical record. This means people outside the research such as health insurers, health care providers, and anyone you have given permission to access your records may be able to find out you participated in this study.

The link between your identifiers and the research data will be destroyed (at the end of the study).

The information and/or samples collected as part of this research will not be used or distributed for future studies.

What if you want to stop being in this study, or if the researcher decides you should no longer participate?

While you are taking part in this study, we may learn new information about Buffered Lidocaine and its use during prostate biopsies. If this happens, we will contact you about the new information so you can decide if you want to stay in the study.

If you decide you want to stop being in this study, be sure to contact the study team. If you fail to complete the surveys prior to the biopsy, we can choose to end your participation in the study.

Will you get to know your research results?

You will not be told what type of treatment you received (Buffered Lidocaine versus Lidocaine). This is to maintain blinding and ensure that your survey results are not affected by knowledge of what treatment you received.

In the rare situation that you develop an adverse event, we will notify you and all healthcare providers taking care of you as to your treatment (Buffered Lidocaine versus Lidocaine).

Other information about this study.

We are **not** receiving financial support or funding from any companies for this study.

If you have been injured or otherwise harmed by participating in this study, contact a member of the research team at azhu5@uw.edu or 949 633 6048. If you are injured as a result of being in this study, necessary medical treatment will be available to you at University of Washington.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

A description of this clinical trial will be available on https://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.

We plan to enroll 300 people in this study

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat

Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher(s) listed in this consent form.

Consent presenter statement

By printing my name on this form, I am attesting that I have provided the subject with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Date

Subject's statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form. I give permission to the researchers to use my medical records as described in this form.

Printed name of subject Signature of subject Date