Hartford HealthCare

Informed Consent for Research

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You have been asked to participate in the research study, "Postoperative Tizanidine Use in Pelvic Reconstructive Surgery: A Pilot Study." This research study is expected to last about 24 months. You have been asked to take part because you are to undergo pelvic reconstructive surgery. If you agree to participate, you will be one of about 186 people taking part at Hartford Hospital.

The Hartford HealthCare Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

The purpose of this research is to find out if adding an additional medication, tizanidine, to standard pain treatment after pelvic reconstructive surgery improves pain control and recovery. Tizanidine is a muscle relaxer that helps alleviate muscle spasm which can impact perceived post-operative pelvic floor pain and recovery, and is an FDA approved medication. We also want to see if it reduces the need for opioid medications and improves overall patient experience after surgery.

A.2. What procedures are involved with participation in this research study?

If you agree to participate:

- You will be assigned by chance ("randomization", like flipping a coin) to one of two groups: standard pain treatment alone or standard treatment plus the additional medication, tizanidine.
- If you are assigned to the treatment group, you will take 4 milligrams of tizanidine three times a day for two weeks. If you are assigned to the standard treatment (control) group, you will receive standard pain treatment.
- Regardless of your group, you will complete surveys about your pain and recovery before surgery, shortly after surgery (day 1–2), at 2 weeks, and at 4–6 weeks after surgery.
- Some of your medical information will be collected from your medical record.
- Study staff may contact you to remind you to complete surveys or ask questions about your recovery if they have not been completed electronically using the provided preferred phone number within a few days of expected survey completion

A.3. Which of these procedures is experimental?

The entire study is experimental.

A.4. Where will participation take place?

Participation will take place at the Hartford HealthCare Urogynecology clinic and hospital where your surgery is performed for the surveys that occur 1-2 days after surgery. The surveys at 2 weeks and 4-6 after surgery may be completed at your home, electronically or by phone.

A.5. How long will participation last?

Your participation will last approximately 4–6 weeks after your surgery.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

Possible risks in taking tizanidine include:

Common (more than 10%):

- somnolence (sleepiness/drowsiness, which may occur during the day)
- dry mouth
- dizziness
- fatigue
- low blood pressure

Uncommon (1-10%)

- increased muscle spasm or tone
- syncope (fainting)
- bradycardia (abnormally slow heart beat)

Rare (less than 1%):

- signs of liver irritation/liver strain
- hallucinations
- severe allergic reactions

Possible risks for both groups include a small risk of loss of confidentiality (protection of data is discussed in Section H) and the inconvenience of completing surveys.

To reduce risks:

- You will be carefully screened before enrollment
- Study staff will monitor you for side effects
- You will be contacted after starting the medication to check for symptoms
- The medication can be stopped if side effects occur
- Your data will be stored securely and only accessible to authorized staff

C. There are possible benefits to you or others to be expected from your participation in this research.

You may not receive direct benefit from participating. If you receive the additional medication, you may experience improved pain control and recovery, but this cannot be guaranteed. Regardless of group assignment, your participation may help improve postoperative care and reduce opioid use for future patients.

D. There are alternatives to participation in this study that you should consider.

If you choose to not participate, you will receive the usual standard postoperative care and medications your surgical team routinely prescribed. Your care will not be affected in any way by your decision not to participate.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	Sindhura Vallabhaneni, MD	860-972-4338
your rights as a research participant	An IRB Representative	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford HealthCare.

G. You will receive financial compensation for your participation in this research.

Your mailing address will be collected for payment via gift card to be sent. Each participant will receive a $20 gift card after completing the first survey at post operative day #1-2 and a second gift card of equal value at 4-6 weeks postoperatively. If you complete the study, you will receive $40 in total.

It will not cost you anything to take part in the study. If you are randomized to the tizanidine group, the medication will be paid for by the study.

A note about the Internal Revenue Service (IRS): Hartford HealthCare is required to report payments of $2000 or more to the IRS. This means that if you receive $2000 or more from Hartford HealthCare during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford HealthCare will protect all the information about you and your part in this study, just as is done for all patients at Hartford HealthCare. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form.

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") Authorization that you will be asked to sign. The study doctor, and under certain circumstances, the United States Food and Drug Administration (FDA), and the Institutional Review Board (IRB) will be able to inspect and copy confidential study specific records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified

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 Website will include a summary of the results. You can search this at anytime.

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

If you have medical insurance, Hartford HealthCare will collect fees for medical treatment at Hartford HealthCare from your insurance company. If you are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford HealthCare will cover these expenses.

There is no plan for Hartford HealthCare to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

J. Authorization to Use and Disclose Information for Research Purposes

Federal regulations (HIPAA Privacy Rule) 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.

What information may be used and given to others?

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 questionnaires completed as part of this research
- Records about your study visits and the results of testing your past study participation. This information will include measures of your physiology. We will also gather information from self-report measures of emotional distress, your diagnosis or diagnoses, and demographic information.
- Information about your treatment from our clinic database. This information will be limited to your age, BMI, ethnicity, parity, marital status, years of education, medical comorbidities, smoking history, menopausal status, ASA physical status classification, surgical information your diagnosis or diagnoses, your routine care, any readmissions, clinic visits, and telephone encounters, and emergency room visits

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and study staff. They might see the research information during and after the study.

Who might get this information?
Information about your health that might identify you may be given to:
• The U.S. Food and Drug Administration (FDA)
• Department of Health and Human Services (DHHS) agencies
• Governmental agencies to whom certain reportable diseases must be reported
• The Hartford HealthCare Institutional Review Board (IRB) and representatives of the Human Research Protection Program (HRPP)

Why will this information be used and/or given to others?
Information about your health that might identify you may be given to others to carry out this research study and other possible research studies if you agreed to the use of your information for future research, as described in this research study consent form. The study team will analyze and evaluate the results of the study. The information may be given to the FDA. The information may also be used to meet the reporting requirements of governmental agencies.

Informed Consent for Research
The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed. The information may be reviewed by the HHC IRB. An IRB is a group of people that perform independent review of research as required by regulations to protect the rights and welfare of human subjects involved in research. No data or information is completely secure. Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

What if I decide not to give permission to use and give out my health information?
By signing and dating this authorization form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. You may not be able to review some of your records related to the study until after the study is over. When the study is over, you may contact the study doctor to see your health data from the study and to correct any errors.

May I withdraw or revoke (cancel) my permission and participation in the study?
This permission will remain in effect from the date of your electronic signature. There is no expiration of this authorization. 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 listed on the first page of this form. If you withdraw your permission, you will also be withdrawn from the study. When you withdraw your permission, no new health information that 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.

Contact Preferences

While we will make every effort to protect your privacy we also realize the importance of being able to contact you about your participation in this research study. This can sometimes mean exchanging information by phone, text, or email. We'd like you to tell us what way is best for reaching you and what information is permitted to be exchanged.
Please indicate below your preferred method(s) to be contacted:

Mark all that apply.

Can we contact you by phone or email? (Circle **all** that apply) PHONE / EMAIL

Phone: (_____) _____-_____

Is it ok to leave voice mail reminders? YES / NO

Is it ok to send text messages about your reminders to this number? YES / NO

Can we contact you by email? YES / NO

Patient email address: _____

We would like to contact you by email or phone for the purposes listed below. Some of these emails may contain health information that identifies you.

- Survey reminders with links to survey
- Information related to this research project

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact our office at (860) 972-4338.

You should be aware that there are risks associated with sending your health information via email/phone.

- There is always a risk that the message could be intercepted or sent to the wrong email address.
- To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.

- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your protected health information via email/phone?

_____Yes (Initials) _____No (Initials)

K. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, "Postoperative Tizanidine Use in Pelvic Reconstructive Surgery: A Pilot Study", and that you consent to the performance of the procedures listed above.

Participant's Signature	Printed Name	Date
Person Obtaining Participant's Signature	Printed Name	Date
Witness signature	Printed Name	*Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally. Required if patient is Spanish speaking.)