Placing Numbing Medication Over Diaphragm to Reduce Shoulder Pain After Gynecologic Surgery: A Randomized Control Trial

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CONSENT FORM FOR RESEARCH
For Cedars-Sinai Medical Center

Study title: Instillation of bupivacaine with epinephrine over diaphragm to reduce postoperative shoulder pain following benign gynecologic laparoscopic surgery: A randomized control trial

Sponsor: Cedars-Sinai Medical Center

Cedars-Sinai Principal Investigator: Kelly Wright, MD

Cedars-Sinai study contact phone number:

Cedars-Sinai after-hours emergency contact (24 hours): (310) 859-6713

To help guide your review of this form, the main sections include:

1. Key Information

Thank you for considering research participation. Research helps make medical and scientific advancements possible. In this form, we are asking for your consent to take part in this research study. Taking part in this research study is voluntary.

This section provides key information about the study. Please take your time to read this entire form. Also, please ask questions before deciding whether to take part in this research study. You are welcome to talk with family, friends and other healthcare providers before you decide.

- **Purpose:** The purpose of this study is to test whether instillation of bupivacaine with epinephrine below the diaphragm, compared with standard of care, will reduce shoulder pain when undergoing benign laparoscopic gynecologic surgery.

- **Duration:** Taking part in this study will last 2 weeks.

- **Procedures:** The main things that will happen in this study are possibly having bupivacaine with epinephrine instilled over your diaphragm during your surgery, being asked questions about your pain in the recovery room, and notifying your provider about the amount of pain pills you take after surgery. Section 4 includes more details.

- **Benefits:** The possible benefits of taking part in this study are improved pain after surgery, if you are assigned to the treatment group. Section 3 includes more details.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study may be infection on the site or common side effects from bupivacaine. Section 6 includes more details.
    - If you experience side effects or have problems during the study, contact the study team using the contact information on the first page of this consent form.

- **Alternatives:** You can choose not to be in the study. There may be other choices for you. These are described in Section 9 of this form.

- **New Information:** During the study, we may find out new information about this study. We will tell you about any important changes or new findings that may impact your decision to continue taking part in the study.

2. Purpose of the Study

We are doing this study to test whether instillation of bupivacaine on the diaphragm reduces shoulder pain more effectively. After laparoscopic gynecologic surgery, many patients experience uncomfortable shoulder pain. While local anesthetics like bupivacaine are commonly used to manage pain, there's been no research on instillation directly onto the diaphragm to reduce shoulder pain. Since the diaphragm is linked to shoulder pain after

surgery, targeting it directly could improve pain relief and lead to a better recovery experience for patients making it more effective than current pain management.

Bupivacaine is being used "off-label," which means the drug is approved by the FDA but is being used in a way that differs from FDA approval.

You are being invited to take part in this research study because you are, or have been, receiving care at Cedars-Sinai within the Minimally Invasive Gynecologic Surgery division for endometriosis.

There will be a control group for the study, which means that half the patients will not receive this drug being studied.

The study will include 200 people in total.

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the table of procedures. The table is given with this consent form.

The table of procedures shows:

- When study procedures will occur,
- Which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** are routine care generally given to people with your condition. They would be performed even if you did not take part in this study. The researchers will schedule the visits and procedures at the listed timepoints.

Section 6 describes the common medical procedures that will be done or repeated only because you are in this research study.

Description of main research procedures:

This study has 2 study groups:

- No intervention
- Bupivacaine with epinephrine

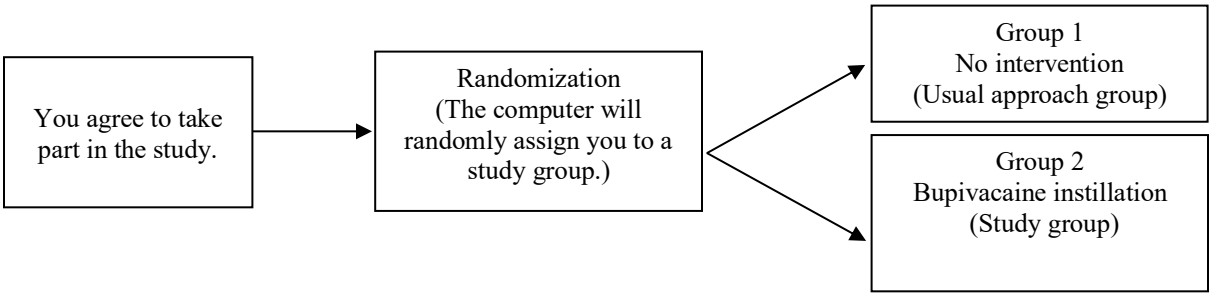
This is a randomized, double blind research study. Here's a breakdown of what these words mean:

- **Randomized**: This means that you will be put in a study group by chance (like flipping a coin). You will be randomly put in one of the above study groups. You will have a one in two

chance of being placed in any one of the groups described above. A computer will randomly put you in a study group. We do this because no one knows if the results in one study group will be different than the others. The results could be better, the same or worse than the results in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.

- **Double-blind:** This means that the researchers will not know which group you are in. You will also not know which group you are in.

You can review the chart below to see what will happen during the study.



People in the control group will be given standard of care. We will collect data on your care.

How long will you be in the study?
We think you will be in this study for about 2 weeks after your surgery. This includes two time points: 1) Day of surgery and 2) 2-week post-operative visit or check-in. We do not anticipate this will take any more time than your routine-postoperative care.

4. Possible Benefits From Taking Part in the Study

Being in this research study may or may not have direct medical benefit to you. The possible benefit of taking part in this study is less pain after surgery, if you are assigned to the study treatment group. If you have less pain after surgery, you may have a faster recovery and may end up using fewer strong pain pills (which can have bad side effects and become addictive). However, no benefit is guaranteed.

We hope the information learned from this research study will help the medical community understand the effects of bupivacaine sprayed over the diaphragm and improve pain after these procedures.

5. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and discomforts of the main study procedures.

The most common adverse reactions associated with Bupivacaine with epinephrine treatment are site reactions, blurred vision, abnormal heart rhythms, anxiety, and chest pain, nausea, vomiting, and chills.

Risks of common medical procedures being done for research purposes are described below in Section 6. Side effects and risks of standard of care procedures are not described in this consent form.

Unknown Risks
There may be other risks that we cannot predict. Many complications are minor and do not last long.

6. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. That said, for this study these procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Bupivacaine with epinephrine **instillation** We may provide instillation of bupivacaine over diaphragm following benign gynecologic laparoscopic surgery.	Risk may include potential interactions between ergot medications, blood thinners, antidepressants, or monoamine oxidase inhibitors.
Physical Exam: We will measure your height, weight and vital signs (heart rate and blood pressure).	This does not have any physical risks.
Medications: We will ask you about your past and current medications. Talk with the study team about any non-study medications. Non-study medications include any prescription drugs, over-the-counter drugs, supplements and vitamins.	This does not have any physical risks.
Demographic Information: We will ask you about demographics, which may include your age, gender identity, sexual orientation, race and ethnicity.	This does not have any physical risks.
Medical History Review: We will ask you about your medical and surgical history. We will also ask about your smoking and alcohol habits, physical activity and menopausal history (as applicable).	This does not have any physical risks.
Questionnaire: You will be asked to complete questionnaires We will ask you questions to find out pain scores post-operation and post-operative opioid use. We	The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.

think it should take about 5-7 minutes to complete the questionnaires.	

7. Reasons Participation May Be Stopped by the Researcher or Sponsor

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. If your participation is stopped early, the study doctor will discuss next steps with you. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

8. Voluntary Participation and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

9. Confidentiality Protections

General Confidentiality

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)

- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Protections From Forced Disclosures (Subpoenas) – Certificates of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence, unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research, if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

10.Research-Related Illness or Injury

Contact in Case of Illness or Injury

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. As needed, your study doctor will treat you or refer you for treatment. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?
Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and copayments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Financial Assistance Program. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

11. Financial Considerations

Costs of Participation
You and your insurance company will not be charged for your participation in this research study. The Study Sponsor will cover the cost of all items, drugs and services required by this study. This includes any procedures required by the study that may be standard of care.

Payment
You will not be paid for taking part in this research study.

Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

12. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH
FOR CEDARS-SINAI AFFILIATED COVERED ENTITIES[1]

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Bupivacaine over diaphragm in laparoscopy" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☒ Pathology reports
☐ Imaging reports (e.g., x-rays or scans)
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Billing records
☐ Photographs or videos of your image
☒ Demographics, which may include, but is not limited to, age, gender identity, race, ethnicity, and/or sexual orientation
☐ Mental health records
☐ Substance abuse records
☐ HIV test results
☒ Other tests or other types of medical information: Pain assessment scores

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

[1] The **Cedars-Sinai Affiliated Covered Entity ("ACE")** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness
(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter,

study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subjects who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Interpreter/Witness name (please print)	Signature	Date