Official Title:Extended Release Local Anesthetic for Postsurgical Pain After Posterior Colporrhaphy and Perineorrhaphy: A Randomized Controlled Study
NCT03875664
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CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title: **Carolinas HealthCare System-Department of OB/GYN / Extended Release Local Anesthetic for Postsurgical Pain After Posterior Colporrhaphy and Perineorrhaphy: A Randomized Controlled Study**

Protocol Number: **(02-18-06)**

Principal Investigator: (Study Doctor) **Sarah Evans, M.D.**

Telephone: [redacted] **(24 hours)**

Address:

Carolinas HealthCare System
Women's Center for Pelvic Health
[redacted]

Carolinas HealthCare System
Carolinas Healthcare System NorthEast
[redacted]

Carolinas HealthCare System
Carolinas Medical Center - Mercy
[redacted]

Carolinas HealthCare System
Women's Center for Pelvic Health - NorthEast
[redacted]

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

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INTRODUCTION

The Women's Center for Pelvic Health is asking you to participate in this research study of extended-release liposomal bupivacaine (Exparel) at the time of your surgery to repair damage to your vagina and/or the area between your vagina and anus (called a "posterior repair") at Carolinas HealthCare System (CHS). Exparel is a long-acting local anesthetic medication that was approved by the U.S. Food and Drug Administration (FDA) for the treatment of postsurgical pain in 2011. You are being asked to take part because you are scheduled to undergo a possible posterior repair for your pelvic organ prolapse. The purpose of this study is to see if injection of a long-acting local anesthetic medication in your incision at the time of surgery will improve your pain control, decrease your need for narcotic pain medications, decrease your chance of going home with a catheter, help you have a bowel movement after surgery, decrease your time in the post-surgery recovery area, and improve your satisfaction with surgery and pain control overall. We know that injection of Exparel at the time of hemorrhoid surgery significantly improves pain control and decreases narcotic use. We also know that injection of short-acting local anesthetic helps with pain control for a few hours after posterior repair. We think that Exparel may work better because it works for over 72 hours compared to 7 hours with short-acting local anesthetic. We often use Exparel now as standard of care during posterior repair but would like to study our outcomes (how it affects our subjects). You will be one of approximately 72 people involved in this research project at CHS, and your participation will last for up to 2 weeks after your surgery date.

HOW THE STUDY WORKS

If you agree to be in the study, you would be randomized to one of two treatments. Being randomized means that you are put in a group by a chance process, like flipping a coin. You won't know what group you are in and neither will your study doctor. We are using this method because it is not clear at the present time if this medication is helpful. Your chance of receiving either treatment is equal.

Although you and your study doctor will not know which study treatment you are receiving, this information can be determined in the event of an emergency.

If you agree to participate, you will be randomized in the operating room to receive either:

- Group 1: Liposomal extended-release bupivacaine (Exparel)
- Group 2: Normal saline (sterile salt water)

One of these medications will be injected into your posterior repair incision site while you are still asleep under anesthesia in the operating room. You will then be asked to record your vaginal pain/discomfort scores every evening and every morning for the first 3 days after surgery, starting the night of surgery. You will also be asked to complete a medication diary during the first 3 days after surgery. You will bring your vaginal pain/discomfort scores and your medication diary back to clinic with you for your postoperative visit. A member of the research team will call you 1-2 times to remind you to do this.

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At your postoperative visit, you will be asked to complete a short (3 question) survey about your satisfaction with your pain control and your satisfaction with your overall experience with surgery.

This study will not require any additional follow-up visits. Your involvement in this study will be completed after your first postoperative visit.

If you choose not to participate in this study, you may still receive an injection of Exparel in your posterior repair incision during surgery at your surgeon's discretion as this is sometimes done as standard of care if your surgeon thinks it will help with your pain control. Everyone - even participants in the placebo group (Group 2) - will receive an injection of SHORT acting local anesthetic medication in their incision at the beginning of surgery. Additionally, we will treat your pain after surgery with pain medications by mouth or through your IV as needed, regardless of which group you are in.

RISKS

The study has several risks. First, you may be in the placebo (inactive medicine) group. In that case you may not receive any long-acting local anesthetic medication (Exparel), although you will still receive short-acting local anesthetic medication at the beginning of surgery. Second, it is possible that you will get the long acting medication but do less well than you would have been doing if you did not receive it. Third, the known side effects of the Exparel are:

Likely (greater than or equal to 10%)

- Nausea
- Constipation
- Vomiting

Less Likely*

- Pain at injection site
- Bleeding at injection site
- Hematoma (blood clot formation at incision site)
- Infection

Rare but serious*

- Persistent numbness after surgery
- Abnormal heart rhythms

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- Allergic-type reactions - as with all medications, side effects may include allergic reaction. Allergic reactions may range from minor itching or rash to major reactions which can result in death.

*These "Less Likely" and "Rare but Serious" risks are risks of local anesthetics in general, and not unique to the study drug.

If you have problems that might be related to the study drug, your study doctor may "break the code" to find out which group you are in. You would then no longer be in the study.

As with all studies that collect personal health information, there is a risk of possible loss of confidentiality with registries. We will take every precaution to make sure your personal health information is kept confidential. This will include keeping any paper data in locked secure cabinets in the hospital and storing any electronic data on secure servers. We will also destroy any identifying information as soon as all of the data is collected. We will not report our data with any information that could be linked to your identity.

EXCLUSION CRITERIA

- Planned regional anesthesia (for example, spinal or epidural)
- Allergy or contraindication to bupivacaine
    - Severe liver disease
    - Pregnant or breastfeeding
- Allergy or contraindication to opioids
- Allergy to contraindication to non-steroidal medications (for example, ibuprofen, Excedrin, Motrin, Aleve)
- Non-English speaking
- Inability to provide consent/decisionally impaired
- Planned laparotomy (open surgery)
- Chronic pain diagnosis
- Chronic narcotic use (daily for 3 weeks or more)

BENEFITS

This study drug may or may not improve your pain control. The information gained from your case may benefit others undergoing this surgery. We believe that this study drug will improve postoperative pain control, reduce narcotic pain medication use and related side effects, improve your ability to walk and be active after surgery, help you pass your voiding trial sooner after surgery, possibly shorten hospital stay, and improve your satisfaction with surgery overall.

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ALTERNATIVE PROCEDURE/TREATMENT

If you choose not to be in this study, you will still receive an injection of local anesthetic medication (either short or long acting at your surgeon's discretion) at the time of surgery. You will receive the same surgical procedure and the same treatment after surgery, including pain medications as needed by mouth or through your IV. You will also have the same postoperative follow-up in clinic. You should talk with your study doctor about your options and their risks and benefits.

ADDITIONAL COST

The study drug (Exparel) is more expensive than short acting local anesthetic medications. In our experience this cost is included in the lump sum hospital/surgical cost so that our subjects do not pay any more than the previously determined price for surgery according to their insurance coverage. If you are paying for your surgery out of pocket however, you may be responsible for this additional cost. Your insurance company may not pay for research treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

COMPENSATION FOR INJURY

If you become ill or are hurt while you are in the study, get the medical care that you need right away.
In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

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- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION ABOUT THE STUDY
We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY:
The records of this study will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by the drug manufacturer, by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

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 DISCLOSE HEALTH INFORMATION
If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigator, Dr. Sarah Evans, and research staff,
- regulatory or other governmental authorities of the United States and other countries,

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- other persons authorized by the study sponsor,
- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your treatment with the study drug,
- compare and pool treatment results with those of other subjects in clinical studies.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. 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 Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor in writing at the address and telephone number on the first page of this form. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

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STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

The doctors will receive no financial benefit in any form by asking you to participate in this study. The doctors will receive no benefits in any form from the company that manufactures the drug being tested in this study.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Carolinas Healthcare, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the study subject adviser: Pro00024327.

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STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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