Cleveland Clinic
Consent to Participate in a Research Study

Study Title: Comparison of Bilateral Transversus Abdominis Plane Block with Exparel versus Continuous Epidural Analgesia With Bupivacaine: A Randomized, Controlled Trial

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Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.**

This research was approved by the Institutional Review Board (IRB). The IRB is a committee that reviews human research studies to ensure the safety and welfare of research volunteers are protected in accordance with federal human subject regulations and ethical principles.

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1. CONFLICT OF INTEREST DISCLOSURE

One or more of the Investigators conducting this study serve as paid speakers, consultants or advisory committee members for the company that is paying for this research or a company that makes products used in this study. These financial interests are within permissible limits established by the Cleveland Clinic Conflict of Interest Policy. If you have any questions, please ask your study doctor or call the Institutional Review Board at 216-444-2924.

2. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are being invited to participate in this study because you are scheduled for elective abdominal surgery.

Why Is This Study Being Done?

Many patients have pain after abdominal surgery. Nerve blocks can reduce the pain. One type is called an epidural block and involves a continuous infusion of local anesthetic near the spinal cord. Another is called a transversus abdominis plane (TAP) block which involves injecting a long-acting local anesthetic between abdominal muscles in 2 points on each side. The long-acting local anesthetic is Exparel, an FDA-approved drug. The main purpose of the study is to compare pain relief with continuous epidural blocks and TAP blocks with a long-acting local anesthetic.

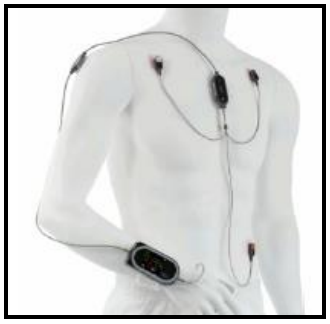
How Many People Will Take Part In The Study?

A total of 640 people will take part in this study at the Cleveland Clinic and other medical centers.

What Is Involved In The Study?

If you agree to take part in this study, you will be randomized (like flipping a coin) to either TAP blocks on each side of your abdomen or an epidural catheter inserted at your mid-back The assigned block will be performed before surgery by an experienced anesthesiologist. You will be given local anesthesia and, if necessary, mild sedation. After surgery, if your anesthesia provider finds it appropriate, you will be given control of a pump that will give you intravenous pain medications as needed.

We will collect information about your recovery from your medical record. A member of the study team will approach you on each of the first 3 days after surgery and ask about pain, anxiety, quality of your recovery, and overall satisfaction. Your blood pressure, heart rate, electrocardiogram, posture, activity and blood oxygen saturation will be continuously monitored using a wireless device which is external to your body and causes no pain (see figure). Three months after surgery, you will be called and asked questions about pain and your recovery over the phone. This conversation will take less than five minutes.



2. RISKS AND DISCOMFORTS

Both epidural and TAP blocks are routine and commonly used. They have different potential benefits and risks, but one is not obviously better or safer than the other.

Potential side-effects of epidural blocks:
- Low blood pressure
- Temporarily decreased strength and sensation of the legs which can cause a fall
- Headache
- Intravenous injection of local anesthetic, that can lead to ringing in the ears, anxiety, dizziness or very rarely to seizures or heart rate problems
- Infection of the epidural space or spinal cord
- Bleeding around the spinal cord which may require surgery
- Damage to nerves

Potential side-effects / complications of TAP blocks:
- Intravenous injection of local anesthetic, that can lead to ringing in the ears, anxiety, dizziness or very rarely to seizures or heart rate problems
- Bleeding around the site of injection
- Puncture of intra-abdominal organs, that might cause infection or bleeding

3. BENEFITS

Are There Benefits To Taking Part In The Study?

There is no direct benefit to you for your participation in this study. Knowledge gained from this research may help determine the efficacy of different pain control approaches after abdominal surgeries.

4. ALTERNATIVES

What Other Options Are There?

The alternative is to not participate in the study. If you do not participate, you will receive standard anesthesia and post-operative pain management which may include either epidural or TAP blocks. You can also stop being in the study at any point.

5. PRIVACY AND CONFIDENTIALITY

The medical and research information recorded about you will be used within the Cleveland Clinic and/or disclosed outside the Cleveland Clinic as part of this research. Tests and procedures done solely for this research study may be placed in your medical record to indicate your participation in this study. Upon completion of the study, you may have access to the research information if contained in the medical record.

Your access to research information about you will be limited while the study is in progress. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information to treat you best.

Your research information may be shared with the Cleveland Clinic research staff, the U.S. Food and Drug Administration and the Department of Health and Human Services. The Cleveland Clinic also may use and disclose this information for treatment and payment reasons. The Cleveland Clinic must comply with legal requirements that mandate disclosure in unusual situations. Otherwise, the information recorded about you as part of this research will be maintained in a confidential manner. It is possible that information disclosed about you outside the Cleveland Clinic could be re-disclosed and no longer protected by federal privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to Dr. Alparslan Turan, at The Cleveland Clinic Foundation, 9500 Euclid Avenue, Mail Code P-77, Cleveland, Ohio 44195. At Fairview General Hospital write to Azfar Niazi, MD 18101 Lorain Avenue Cleveland Ohio 44111. At Hillcrest Hospital write to Manal Hassan, MD 6780 Mayfield Road, Cleveland Ohio 44124.

If you do so, any information previously disclosed cannot be withdrawn. The Cleveland Clinic will not use or disclose the information collected in this study for another research purpose without your written permission unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects.

If you choose not to sign this consent form, you will not be permitted to participate in this research study.

6. RESEARCH RELATED INJURIES
What Happens If An Injury Occurs?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form.

Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. COSTS
What Are The Costs?

There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

8. VOLUNTARY PARTICIPATION
What Are Your Rights As A Participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

9. QUESTIONS
Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact **Dr. Alparslan Turan** at 216 445-9857 or the Department of Outcomes Research at 216-445-6500 and after hours at 216-312-9526. For patients being seen at Fairview General Hospital contact **Azfar Niazi, MD** at 216-476-2275 and after hours at 216-476-7056. For patients being seen at Hillcrest Hospital contact **Dr. Manal Hassan** at 440-312-5259. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. SIGNATURE

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date