

**Cleveland Clinic Florida
Consent to Participate in a Research Study**

Study number: FLA 18-088
Study title: Lidocaine and ketamine in abdominal surgery
Principal investigator: Rebecca Yuen Shi Wong, MBBS MPH
954-789-8933 or wongr3@ccf.org

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **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 anytime.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

- You are being asked to participate in the research study as you are scheduled to have abdominal surgery.
- The purpose of the study is to determine whether adding lidocaine and/or ketamine to routine pain treatment reduces pain after abdominal surgery.

What is involved if you decide to take part in this research study?

- You will be randomly (like flipping a coin) be given lidocaine, ketamine, the combination, or a placebo. Neither you nor your physicians can choose the group assignment, and neither party will be told to which group you have been assigned.
- The study drug(s) or placebo will be given with other fluids throughout the surgery and the first hour or so of your recovery period.
- You will be asked certain questions before you leave the recovery area, on the morning of the first day as well as on the morning of the second day after surgery.
- Study information will also be collected from your medical record.
- If you are discharged from the hospital before the morning of the second day after surgery, you will receive a phone call from one of our team members asking you these questions.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

- You will receive the same standard of care regardless of research participation.

3. RISKS

What are the risks of participating in the research study?

- The medication lidocaine may have the following adverse effects:

	Mild	Moderate	Severe
Likely > 5 %	<ul style="list-style-type: none"> • Drowsiness • Nausea or vomiting 	<ul style="list-style-type: none"> • Confusion 	
Less Likely < 5 %	<ul style="list-style-type: none"> • Numbness or tingling • Ringing in the ears 	<ul style="list-style-type: none"> • Heart rate or rhythm abnormalities • Blood pressure abnormalities 	
Rare < 1 %	<ul style="list-style-type: none"> • Twitching or tremors • Dizziness 	<ul style="list-style-type: none"> • Blurred or double vision • Seizures 	<ul style="list-style-type: none"> • Allergic reaction • Respiratory arrest • Cardiac arrest

- The medication ketamine may have the following adverse effects:

	Mild	Moderate	Severe
Likely > 5 %	<ul style="list-style-type: none"> • Drowsiness • Nausea or vomiting 	<ul style="list-style-type: none"> • Confusion • Vivid dreams • Hallucinations 	
Less Likely < 5 %		<ul style="list-style-type: none"> • Heart rate or rhythm abnormalities • Blood pressure abnormalities 	
Rare < 1 %	<ul style="list-style-type: none"> • Twitching or tremors • Rash • Loss of appetite 	<ul style="list-style-type: none"> • Blurred or double vision 	<ul style="list-style-type: none"> • Allergic reaction • Respiratory arrest • Cardiac arrest

- Patients 65 years and older are at higher risk of confusion after surgery, but it remains unclear if either medication increases this risk.
- If you are placed in the control group, you may not receive any benefits from the treatment that is being studied.
- Access to your data is limited to the research team, and will be securely stored.

4. BENEFITS

What are possible benefits of participating in the research?

- You may benefit from the research by having less pain after the surgery.

5. COSTS

Are there any costs to you if you participate in this study?

- Some of the services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your

health insurance plan. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

6. COMPENSATION

Are there any payments to you if you participate in this study?

- No.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

- This is a minimal risk study.
- There may be risks or side effects related to the study drugs that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.
- 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.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

- The studies described are for research purposes only. It is not the purpose of these studies to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research studies.
- Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.
- The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.
- Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.
- You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.
- You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing (**Dr. Rebecca Wong** wongr3@ccf.org). If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information

about you will be collected. Your cancellation would not affect information already collected in the study.

9. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?

- There are no conflicts of interest.

10. QUESTIONS

Who do you call if you have any questions or problems?

- You may contact the principal investigator, Dr. Rebecca Wong, at 954-789-8933 or wongr3@ccf.org.

11. VOLUNTARY PARTICIPATION

What are your rights as a research 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.
- Some of the questions asked as part of the study may make you feel uncomfortable. You may refuse to answer any of the questions. There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards; storage on the hospital network drive and communication using only hospital emails.

12. SIGNATURES

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

Statement of Interpreter (if applicable)

I interpreted the information contained in this document into the participant's stated primary language as well as any questions and answers raised during the informed consent discussion.

Printed name of interpreter

Signature of interpreter

Date