IRB #: IRB18-00920
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"ICE-T" Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Laparoscopic Gynecologic Surgery: a Randomized Controlled Trial

Introduction

You are being asked to participate in this research study "ICE-T" Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Laparoscopic Gynecologic Surgery: a Randomized Controlled Trial. Before you can decide whether or not to volunteer for this study, you must be informed of the purpose of the research study, how this study may help you, any risks to you, and what is expected of you. This process is called informed consent.

You do not have to participate in this study. You may stop your participation in this study at any time without changing your current or future relations with MetroHealth Medical Center or its doctors.

If you decide to participate in this study you will be told about any new information learned during the course of the study that might cause you to change your mind about staying in the study. If you withdraw we will still provide you with information regarding possible impacts to your health status or future health care decisions.

Why is this study being done?

The purpose of this study is to determine if use of ice packs and Tylenol/Toradol (ICE T regimen) is as effective for pain as narcotic/opioid use after laparoscopic gynecological surgery.

66 total patients will participate in the study.

What is involved in the study?

Frequency of Visits

This study will not require any additional visits other than those already scheduled. You will receive one regimen or another for pain after surgery. After surgery, we will follow you with pain scale scores at 4 hours and 24 hours after surgery and will obtain information about your post surgery recovery. Once discharged, we will call you regarding your well being as far as 96 hours after surgery.

Screening – You are being asked to participate in this study because you meet the screening criteria as set forth by the investigators.

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Randomization/study intervention

Using chance, a method of selection called randomization (similar to a coin toss) will be used. In this study, you will be assigned to one of two treatment groups. The ICE-T group or the Standard group.

Regimen #1 Intervention Group
At the end of surgery patients will receive 30mg of intravenous toradol. Once out of the post anesthesia care unit patients will receive:
1. ICE PACKS applied to the surgical sites every hour for 20 minutes around the clock until discharge.
2. Every 6 hours from the time of first dose patients will receive 30 milligrams of intravenous toradol around the clock until discharge.
3. Once out of the recovery unit, patients will receive 1 gram of oral Tylenol every 6 hours for a total of 4 grams daily around the clock until discharge
4. Patients will receive dilaudid 0.2 milligrams intravenously every 3 hours as needed for breakthrough pain.
5. Patients will be discharged home with oral Tylenol and toradol as needed.

Regimen #2 STANDARD after surgery regimen (Control group)
1. Once out of the recovery room patients will receive “Standard” after surgery regimen
2. Motrin 600 milligrams orally every 6 hours as needed for pain scores of 1-3on pain scale
3. Percocet 1 tablet every 4-6 hours orally as needed for pain score of 4-6 on pain scale 4. Percocet 2 tabs by mouth every 7-10 hours orally as needed for pain score 7-10 on pain scale
5. Patients will receive dilaudid 0.2 milligrams intravenous every 3 hours as needed for breakthrough pain.
6. Patients will be discharged home with oral Motrin and Percocet for pain as needed.

Duration

The entire duration of the study is 4 days in total.

What happens if I discontinue or withdraw from the study?

If you withdraw from the study before its completion, you may be asked to return or dispose of all study medication and, for your safety, to come in for a final study visit in order to ensure you have adequate pain control and continue to meet postoperative milestones.

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Investigator-Initiated Termination of Participation: There may be instances that would require investigators to terminate the participation of particular subjects (e.g., subject non-compliance with research, subject not benefiting from research). We may also stop the study if we notice there is an increase in pain in 10% of patients or more with the ICE-T regimen.

What are the risks of this study?

Your participation in this study may involve the following risks associated with the medications that compose the novel multimodal pain regimen, ICE-T:

Tylenol Risks:
Rare cause of liver toxicity (1% or less)
Rare cause of serious kidney disease (1% or less)
Rare risk of allergic reaction (1% or less)
Rare risk of overdose (1% or less)

ICE
Uncommon risk of hypothermia (>1% to 10%)
Uncommon risk of shivering (>1% to 10%)
Rare risk of wound infections/complications (<1%)

TORADOL
Rare risk of gastrointestinal complications, i.e. bleeding (<1%).
Rare risk of cardiovascular disease (<1%) and contraindicated in setting of coronary artery bypass graft (CABG).
Rare risk of renal disease (<1%) and contraindicated in patients with renal failure
Rare risk of bleeding (<1%) and contraindicated in patients with suspected or confirmed bleeding.
Rare risk of allergic reaction (<1%) and contraindicated in patients with previous reaction to Non-steroidal anti-inflammatory drugs (NSAID)

The ICE-T combination is experimental.

There is a potential risk that the ICE-T after surgery regimen may not control pain as well as the standard regimen.
This study may involve risks that are currently unforeseeable.

Emotional and Psychological Risks –

Some of the questions we ask may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

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Your condition may not improve or may worsen while you are taking part in this study.

We cannot predict all risks or potential side effects. There may be unknown and/or delayed risks that may occur months or years after treatment.

Are there benefits to taking part in the study?

Participation in this research study might be a direct benefit to you. No guarantee of benefit or any other result can be made. The potential benefits to you from participating in this study may include decreased opioid requirement after surgery, improved pain control, decreased nausea and vomiting, and earlier bowel movement. Your participation in this study may aid in our understanding of pain management after laparoscopic gynecologic surgery and may benefit patients undergoing laparoscopic gynecologic surgery in the future.

What other options are there?

This is a research study. You may decide not to participate.

If you do not wish to participate in this study, you will receive the standard before surgery and after surgery medications for your surgery.

What are the costs?

All testing and services of the study will be provided at no cost. You (or your insurance) are responsible for all other costs that are part of your usual medical care and that would have been done regardless of your enrollment in the study. If your health insurance or Medicare requires any co-payment, co- insurance or deductible associated with your usual medical care, you will be responsible for making the payment.

What happens if I am injured while participating in this study?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur during the course of the study, you must contact your study doctor, Dr. Robert Pollard at the (216) 778-4444. Necessary medical care will be provided to you by The MetroHealth System. The MetroHealth System has not set aside funds to pay you for any such reactions or injuries or for the related medical care. This medical care is not free. You and/or your insurance company will be responsible for the costs. However, you can still try to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

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Will I be paid for participating in this study?

You will not be paid or compensated for your participation in this study.

HIPAA:

As part of this study, we are collecting Protected Health Information (PHI) such as: your telephone number, name or initials medical record or prescription numbers and dates related to the individual (e.g. birthday). This information is being collected for the purpose of contacting you and ensuring your safety. All information will be kept on a secure database and in a locked office. Only the study team will have access to these files. The investigators will have access to your PHI collected until data analysis is complete. At that time, the PHI will be destroyed. The study file will be kept for 4 years after study completion, at which time it too will be destroyed. You have the right to withdraw your permission/authorization for us to access your PHI at any time except to the extent the PHI already collected by the investigators before your withdrawal has already been acted upon based on your signed Authorization. No new PHI about you will be collected for study purposes unless required by law.

What about Confidentiality?

We will make every effort to keep your research records private, but confidentiality cannot be assured. The MetroHealth System has no control over the use of this information once it is released.

Records that identify you and this consent form may be looked at by a regulatory agency such as:
The Food and Drug Administration (FDA)
Department of Health and Human Services agencies
MetroHealth Institutional Review Board
National Committee for Quality Assurance

If the results of the study are published or presented in public, your name will not be used.

Centralized Data Collection or Registries

The results of your tests will be stored in a centralized computer or data registry at the OBGYN office at MetroHealth Medical Center, Cleveland, Ohio for 4 years.

What are my rights as a study participant?

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Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, your doctor will still take care of you. You will not lose any benefits or medical care to which you are entitled. If you withdraw from the study, with your written permission, clinical data will continue to be collected from your medical records.

If you chose to take part, you have the right to stop at any time. You will be told of any new findings from this or other studies that may affect your health, welfare, or willingness to stay in this study. By signing this consent form, you do not waive any of your legal rights.

If you are an employee or student, whether or not you take part in this study will not affect your job, current or future medical care, or studies.

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 Web site at any time.

Does MetroHealth or any member of the research team have a financial conflict of interest in this study?

None.

Whom do I call if I have questions or problems?

If you have questions about any part of the study now or in the future, or if you wish to communicate concerns or a complaint you should contact Dr. Robert Pollard who may be reached at (216) 778-4444. If you experience any side effects or injuries while participating in this study, please contact Dr. Robert Pollard who may be reached at (216) 778-4444. For after hours, weekends and/or holidays, please page Dr. Darvish at (216) 207-4933. If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints please contact the MetroHealth Medical Center's Institutional Review Board (which is a group of people who review the research to protect your rights at (216) 778-2021.

Instructions on how to "Page":
Dial: (216) 207-4933 After the beep, enter your phone number followed by the # sign
Hang up
Someone will call you back

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Patient/Subject Acknowledgement:

The procedures, purposes, known discomforts and risks, possible benefits to me and to others, and the availability of alternative procedures regarding this research study have been explained to me. I have read this consent form or it has been read to me, and I have been given the opportunity to ask questions or request clarifications for anything I do not understand. I voluntarily agree to participate in this study. I have been given a copy of this consent form.

_____	_____	_____
Patient/Subject Signature	Date	Time
_____	_____	_____
Signature of Person Obtaining Informed Consent	Date	Time

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