Ottawa Hospital Research Institute
Institut de recherche de l'Hôpital d'Ottawa

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PARTICIPANT INFORMED CONSENT FORM

Title of Study: Randomized, Double-Blinded, Placebo-Controlled Trial to Investigate the Role of Laparoscopic Transversus Abdominis Plane Block in Gastric Bypass Surgery

Local Site Principal Investigator (PI): Dr. Joseph Mamazza (613-798-5555, ext 13151)

Sponsor: The Ottawa Hospital Research Institute

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study doctor and study team as many questions as you like. We encourage you to discuss your options with family, friends or your healthcare team.

Why am I being given this form?

You are being asked to participate in this research project because you will be undergoing bariatric surgery.

Why is this study being done?

This study is designed to find out the good and bad effects of injecting anesthetic called ropivacaine (numbing medicine) into Transversus Abdominis Plane and Rectus Sheath during surgery. Ropivacaine is a local anesthetic used to block pain in the body. Some studies have suggested that ropivicaine decreases pain and post-operative opioid (pain medications) consumption after laparoscopic surgery. ropivacaine has not been tried in bariatric surgery and we are not sure whether its use will make a difference in post-operative opioid consumption following bariatric surgery. We are doing this study to see if we can decrease the amount of post-operative opioids that patients have after laparoscopic gastric bypass. Ropivacaine has been approved by Health Canada for use as a regional block and its specific use is listed in the product monograph supplied by the manufacturer and approved by Health Canada.

We estimate that 150 participants will be enrolled in the study from The Ottawa Hospital- Civic Campus.

How is the study designed?

This study compares the effects of the study drug [ropivacaine] with a placebo [Normal Saline]. A placebo is an inactive substance that looks exactly like the study drug.

Whether you get the study drug or the placebo/comparison will be decided randomly. Randomization means that you are put into a group by chance "similar to flipping a coin".

This study will be double-blinded. That means you will not be told if you will be taking the study product [ropivacaine] or the placebo comparison [Normal Saline]. Your study team will also not know. Blinding helps to remove any bias or pre-conceived notions from affecting the outcome of the study. However, in an emergency this information can be obtained quickly. You may be told once the study is finished.

What is expected of me?

If you decide to be a part of the study, during your visit to the pre-admission unit before your surgery, the study team needs to find out about your health before you receive the ropivacaine or Placebo. This is called the baseline visit. In addition to the results from the baseline, the results of the tests/questions at the baseline visit will help the study team to decide whether you can continue in this study.

You will be asked to complete a Quality of life questionnaire (QoR-40), which will take approximately 10-15 minutes. You may skip any questions that make you uncomfortable or that you do not wish to answer. You will be asked to indicate your current pain level on a numeric pain scale (NRS); this takes less than 3 minutes.

You will be asked to blow into a small machine that looks like an asthma "inhaler" so that we can measure your lung capacity (Peak Expiratory Flow – PEF) this will take about 15 seconds and will be repeated 8 times at different times and will be encouraged to use the provided PEF in the weeks preceding the surgery and the days after your surgery till your first follow-up.

Finally, you will be asked to perform a six-minute walk test where we will measure the distance you are able to walk in six minutes, this will be done 4 times in total between recruitment and the time you finish your first follow-up visit after surgery, you will also be encouraged to practice the 6 minute walk test in the weeks between your enrollment, your surgery and follow-up

As a participant your current therapies or treatments will not be altered or discontinued.

The above variables will be collected at different times and the below tables will indicate the times they will be collected.

Your participation in this study will not require you to visit the hospital out of your normal visits.

Table 1 Study Visits and Procedures

	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	*Pre-Admission Unit Visit*	*1 day before surgery*	*Morning of Surgery*	*Intra-operatively*	*During Your Stay after Surgery*	*At your Follow-up Visit*
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Collection of Baseline Data	X					
Allocation		X				
INTERVENTIONS:						
Ropivacaine				X		
Normal Saline				X		
ASSESSMENTS:						
Numeric Pain level	X		X		X	X
Peak Expiratory Flow	X		X		X	X
Analgesic use	X		X	X	X	X
6 minute walk test	X		X		X	X
Quality of life questionnaire	X		X		X	X

How long will I be involved in the study?

The entire study will last approximately 12 Months. Your participation in the study will last only for the duration between your visit at the preadmission unit before your surgery and to your first follow-up visit one week after your surgery. Over this time, you will be required to visit The Ottawa Hospital on your regular visits.

Your participation in the study may be stopped for any of the following reasons:

- The study doctor feels it is in your best interest.
- You need treatment that would interfere with the study.
- You do not follow the study staff's instructions.
- Mechanical complications occur during surgery that are unrelated to the treatment but may confound post-operative outcomes, e.g. intra-operative hemorrhage, larger spillage of bowel contents, iatrogenic injuries, conversion to laparotomy.

What are the potential risks I may experience?

This study drug has risks, as most drug do.

However, there is always a chance of risks that we do not know about. The risks we know about are listed below.

Some drug side effects can be managed. Most side effects go away when you stop taking the drugs, but others might be long-lasting or permanent.

There are small risks involved in being part of this study. Ropivacaine has been studied in over 600 patients. No toxicities have been seen, so the risk is less than 1/600 (less than 0.1%).

Quality of life Questionnaires:
You might find the interviews and questionnaires tiring if they are quite lengthy. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

Risks of Insurability:

We will take all reasonable steps to keep your research information confidential. Should someone not involved in the research find out that you took part in this research study, or if you choose to share your results (if they are provided to you), there is a possibility that this could affect your insurability under certain policies of insurance, depending on the exclusions in such policies.

Can I expect to benefit from participating in this research study?

If you participate in this study, there may or may not be direct benefit to you. Your participation may allow the researchers to benefit other patients who have bariatric surgery in the future.

This study will select by chance which treatment you will receive. Participants in one arm of this study may do better or worse than participants in the other arm.

Do I have to participate? What alternatives do I have?

You can choose not to participate in this study. If you choose not to participate, this will not affect your medical care in any way. Your study doctor will discuss these options with you.

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting the medical care, education, or other services to which you are entitled or are presently receiving at this institution.

If I agree now, can I change my mind and withdraw later?

You may withdraw from the study at any time without any impact on your current or future care at this institution.

- If you decide to stop your study drug you should contact the study doctor or the study team first. They will discuss the related issues or possible safety concerns for you.
- You may also choose to discontinue your participation in the study. However, a final visit(s) may need to be completed to ensure your safety and well-being.
- If you withdraw your consent, the study team will no longer collect your personal health information for research purposes, unless it is needed for review of safety.

What compensation will I receive if I am injured or become ill in this study?

In the event of a study-related injury or illness, you will be provided with appropriate medical treatment and care. Financial compensation for lost wages, disability or discomfort due to an injury or illness is not generally available. You are not waiving any of your legal rights by agreeing to participate in this study. The study doctor, The Ottawa Hospital and the sponsor still have their legal and professional responsibilities.

Will there be any additional costs to me?

There will be no cost to you for participating in this study. You will be reimbursed for parking directly related to this study, if visits are scheduled outside your regular visits.

How is my personal information being protected?

- If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. "Personal health information" is health information about you that could identify you because it includes information such as your name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures.
- Information that identifies you will be released only if it is required by law.
- All information collected during your participation in this study will be identified with a unique study number (for example participant # AB01), and will not contain information that identifies you.
- Documents or samples leaving The Ottawa Hospital will only contain the coded study number.
- A Master List provides the link between your identifying information and the coded study number. This list will only be available to Dr. Joseph Mamazza and his staff and will not leave this site.
- The Master List and coded study records will be stored securely.
- For audit purposes only, your original medical records may be reviewed under the supervision of Dr. Joseph Mamazza's staff by representatives from:
    - The Sponsor, the Ottawa Hospital Research Institute.
    - Health Canada
    - the Ottawa Health Science Network Research Ethics Board (OHSN-REB)
- You will not be identified in any publications or presentations resulting from this study.
- Research records will be kept for 25 years, as required by Health Canada

- At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

This research study can be found on the above listed website by using the clinical trial registration number NCT03367728

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Do the investigators have any conflicts of interest?

There are no conflicts of interest to declare related to this study.

What are my responsibilities as a study participant?

It is important to remember the following things during this study:

- Ask your study coordinator if you have any questions or concerns.
- Tell your study coordinator if anything about your health has changed.
- Call the study doctor if you experience any side effects, even if you are unsure whether it has anything to do with this study.

Will I be informed about any new information that might affect my decision to continue participating?

You will be told in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Who do I contact if I have any further questions?

If you have any questions about this study or if you feel that you have experienced a study-related injury or illness, please contact Dr. Joseph Mamazza at 613-798-5555 ext.13151. The study staff can be reached at 613-798-5555 ext. 17122.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed this protocol. The Board considers the ethical aspects of all research studies involving human participants at The Ottawa Hospital If you have any questions about your rights as a study participant, you may contact the Chairperson at 613-798-5555, extension 16719.

Randomized, Double-Blinded, Placebo-Controlled Trial to Investigate the Role of Laparoscopic Transversus Abdominis Plane Block in Gastric Bypass Surgery

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about the use of Ropivacaine as Laparoscopic Transversus Abdominis Plane Block in Gastric Bypass Surgery
- This study was explained to me by _____.
- I have read, or someone has read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Investigator/Delegate's Printed Name	Investigator/Delegate's Signature	Date

Assistance Declaration

Was the participant assisted during the consent process? ❑ Yes ❑ No

❑ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, and consent was freely given by the participant/substitute decision-maker.

❑ The person signing below acted as a translator for the participant/substitute decision-maker during the consent process. He/she attests that they have accurately translated the information for the participant/substitute decision-maker, and believe that the participant/substitute decision-maker has understood the information translated.

_____	_____	_____
Name of Person Assisting (Print)	Signature	Date