Comparison Between Serratus Plane Block And Local Surgical Infiltration In Robotic Video Assisted Thoracoscopic Surgery- A Randomised Controlled Trial
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Mount Sinai	Protocol Name:	COMPARISON BETWEEN PECS BLOCK AND LOCAL SURGICAL INFILTRATION IN ROBOTIC VIDEO ASSISTED THORACOSCOPIC SURGERY- A RANDOMISED CONTROLLED TRIAL
	Principal Investigator:	YAN LAI MD,MPH.
	Primary Contact Name/Contact Info:	POONAM PAI B.H MD. [redacted]
	Date Revised:	07/08/2017
	Study Number:	IF2058656/HSM# 17-00611/GCO#17-1294

HRP-503 PROTOCOL TEMPLATE

Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. Provide information if and when applicable, and in cases where an entire section is not applicable, indicate this by marking the section "N/A". Do not delete any sections.
For any items below that are already described in the sponsor's protocol, the investigator's protocol, the grant application, or other source documents, you may simply reference the title and page numbers of these documents in the sections below, rather than cutting and pasting into this document. Do not refer to the Sample Consent document, or information on the application form in this document..
Keep an electronic copy of this version of the document. You will need to modify this copy when making changes.

Brief Summary of Research (250-400 words):

Robotic video-assisted thoracoscopic surgery (VATS) is increasingly being used as it is a less invasive surgery compared to traditional methods, but the acute pain at an early stage after VATS has a major impact on perioperative outcomes. Effective post operative analgesia is believed to reduce morbidity, quicken recovery, improve patient outcome and reduce hospital costs. The site and extent of the incision influences the degree of pain due to disruption of intercostal nerves as well as inflammation of chest wall and pleura. Neuraxial and systemic opioids have been a gold standard as a part of multimodal analgesia for thoracic surgeries. Numerous modalities have been studied: thoracic paravertebral nerve blocks, thoracic epidural analgesia, intercostal nerve blocks, patient controlled analgesia (PCA), cryo-analgesia, transcutaneous electrical nerve stimulation (TENS), inter-pleural blocks, stellate ganglion blocks, long thoracic nerve blocks, and infiltration under direct vision by the surgeon.

Pectoral nerve blocks or PECS block is an emerging regional technique that has proven to be effective in comparison to paravertebral blocks in patients undergoing breast surgery and mastectomy with reduced perioperative opioid consumption and improved pain scores.

The lateral pectoral nerve, medial pectoral nerve, intercostal nerves and long thoracic nerve are all targets for the PECS block. It can be safely performed under ultrasound guidance.

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The purpose of our study is to evaluate the difference in quality of analgesia between efficacy of PECS block and local surgical infiltration by surgeon as measured by patient opioid consumption and pain scores.

1)Objectives

Research Question*:* Does PECS block provide superior analgesia in comparison with surgeon injected local infiltration into the wound in a robotic assisted VATS?

Primary outcome: The amount of opioid consumption (in mg IV morphine equivalents) postoperatively up to 24 hours after the end of procedure. The degree of postoperative pain in terms of VAS at rest and on cough on arrival to PACU, 2 hours later, discharge from PACU, 6 hours, 12 hours, 18 hours and 24 hours after surgery.

Secondary outcome:

Time to first dose of narcotic administration, PACU or ICU length of stay, and patient satisfaction.

2)Background

See above. There have been several studies regarding efficacy of local infiltration of wound in thoracic surgery for pain control. PECS block is a novel technique used in pain control in patients undergoing mastectomy. But there have been no study to date comparing the use of local infiltration and PECS block in thoracic surgery.

3)Setting of the Human Research

Prospective triple blinded randomized control trial undergoing robotic assisted VATS. The research study will take place at Mount Sinai West hospital. The site PI is Yan Lai, MD, MPH.

4)Resources Available to Conduct the Human Research

For n=100, the feasibility of recruitment is manageable. With the HIPAA waiver requested, the surgeon will provide investigators (both of whom are physicians within the department of Anesthesiology) with information of eligible patients. The surgeon will also provide study information (protocol, consent, general information) to patients in the surgeon's office. After the operating room schedule has been reviewed for potential participants in the study the contact information will be obtained through the surgeon's office. Subjects will be called by the department of Anesthesiology when their surgery is scheduled. A member of the research team will contact the patient to explain the study, confirm participation, and answer any questions. On the day of the surgery, the subject will meet the research team in the holding area. The team will finalize participation and ask the subject to sign study consent forms. The staff members on this protocol are all employees of Mount Sinai and will either be a resident or attending physicians that are included on the IRB protocol. There are two primary members of the research personnel:

a)Yan Lai, MD, MPH – Roles for Dr. Lai in this study include serving as primary investigator responsible for study design and planning, data collection, subject recruitment, manuscript writing and preparation, data analysis, safety monitoring, and responding to adverse events and/or complications. He is certified in PPHS/IRB protocols, all Citi/IRB required training in human subject protection, and has prior clinical research experience. He is also a board certified anesthesiologist and assistant professor of anesthesiology with the Icahn School of Medicine and the Mount Sinai Health System.

b)Poonam Pai. B.H MD – Roles for Dr. Pai include serving as primary research coordinator involved in data collection, subject recruitment, manuscript writing and preparation, data analysis, safety monitoring, and responding to adverse events and/or complications. She has completed all of her required CITI training to be IRB certified and has experience in clinical research. In addition she has been a resident physician in anesthesiology with the Icahn School of Medicine in good standing for the previous two years going on her third.

There are institutional processes to ensure that all persons assisting with the protocol will be well informed. The research personnel will conduct regular meetings and department email updates to review the results and safety data of the study. The research personnel will initiate the formation of a safety monitoring board for adverse effects, complications, or complaints from patient subjects.

5)Study Design

Prospective triple blinded randomized control trial. With the HIPAA waiver requested, the surgeon will provide the investigators (both of them are physicians within the Department of Anesthesiology) with information of eligible patients. The surgeon will also provide study information (protocol, consent, general information) to patients in the surgeon's office. After the operating room schedule has been reviewed for potential participants in the study the contact information will be obtained through the surgeon's office. Subjects will be called by the department of Anesthesiology when their surgery is scheduled. A member of the research team will contact the patient to explain the study, confirm participation, and answer any questions. On the day of the surgery, the subject will meet the research team in the holding area. The team will finalize participation and ask the subject to sign study consent forms. All patients will be provided with copies of the IRB protocol and consent if they wish to have it. Copy of the consent form will be sent in a secured email to the potential subject. The email will be secured by entering in [SECURE] in the e-mail subject line. Once recruited blinding assessments will be done by the study team.

Patients will be assigned randomly using a computer-generated table of numbers to either PECS (Pecs group) or placebo (placebo group). Block team will perform all blocks. Resident anesthesiologist will know the group allocation but will not be involved in the study and prepare the placebo and anesthetic solutions. Patients assigned to PECS block group will receive 30ml 0.25% bupivacaine under ultrasound guidance on the side of surgery. Otherwise, the patient, surgeon, and anesthesiologist in the case will be blinded. At the conclusion of the surgery prior to skin closure, all the patients will receive 20ml of local anesthetic infiltration as per surgeon's current practice.

a) Recruitment methods: See above.

b)Inclusion and Exclusion Criteria

Inclusion criteria: ASA (American Society of Anesthesiology) class I-IV, age 18-75.

Exclusion criteria: ASA class V, morbid obesity, patient refusal, patients with chronic pain or on pain medications, allergy to LA, patients receiving any additional regional techniques, coagulopathy, patients receiving systemic anticoagulation, local infection, and procedures anticipated to last more than 5 hours.

c)Number of Subjects

We intend to have an n=100. Based on a confidence level of 95% with a Z score of 1.96, standard deviation of .5 and a confidence interval of 10% our sample size should be 96. For ease of statistical calculations we rounded up to 100 patients. Based on previous literature pertaining to local infiltration in thoracic surgery and postoperative analgesia using PECS block in breast surgery, we found studies included anywhere from 85 to 113 patients which is consistent with our calculations.

$$ss = \frac{Z^2 * (p) * (1-p)}{c^2}$$

Where:

Z = Z value (1.96 for 95% confidence level)
p = percentage picking a choice, expressed as decimal (.5 used for sample size needed)
c = confidence interval, expressed as decimal (e.g., .01= ±1)

Sample size= [(1.96^2)(.5)(.5)]/(.1^2)=96 subjects

For effect size, we expect a Cos d medium effect of 0.5. The estimate for sample sizes was obtained by using the first set of pain scores obtained in the PACU.

d)Study Timelines

2017-2018 and subsequent data analysis. The subject's participation will be from time of enrollment in the pre-operative period until first postoperative day. Estimated date of enrollment completion will be when 100 eligible subjects are enrolled in final data analysis. Estimate date for study completion will be June 2018.

e)Endpoints

The primary endpoints will be the amount of opioid consumption (in mg IV morphine equivalents) postoperatively up to 24 hours after the end of procedure and the degree of postoperative pain in terms of VAS at rest and on cough on arrival to PACU, 2 hours later, discharge from PACU, 6 hours, 12 hours, 18 hours and 24 hours after surgery.

Secondary end points – Time to first dose of narcotic administration, PACU or ICU length of stay, and patient satisfaction.

Conclusion of data analysis and evaluation of significance of findings will follow completion of data collection on primary and secondary outcomes.

f)Procedures Involved in the Human Research

Prospective randomized controlled trial and data analysis only. PECS block and local wound infiltration. Intraoperative care of the patient will be provided by an anesthesia team member who is a part of the Mount Sinai System. The anesthesia provider will not be aware of the randomization of the patient. Standard post-operative orders will be written for patients during their time in the PACU. Orders include oxycodone, fentanyl and hydromorphone.

g)Specimen Banking

N/A

h)Data Management and Confidentiality

Data collected in excel file to be de-identified after initial collection. Excel file be subsequently encrypted and shared only between the two above listed investigators via secure Mount Sinai electronic mail.

The information included in the data will be medical record number, age, gender, ASA class, type of surgery, pain score assessments; time to first narcotic, total narcotic use and pain scores up to 24 hours after surgery. Only the research personnel will have access to the data. The data will be stored as a hard copy files and on a secure spreadsheet. The research personnel is responsible for the receipt of the data. The PI will keep the hard copies secure and any electronic data will be encrypted. No personal identifiers will be used. The data will undergo statistical analysis.

i)Provisions to Monitor the Data to Ensure the Safety of Subjects

Part I: Elements of Data and Safety Monitoring Plan

MSSM Principal Monitor:

Last Name: Lai
First Name: Yan
Academic Title: Attending Physician, Assistant Professor
Department: Anesthesiology
Mailing Address: Mount Sinai West 1000 10th Avenue, New York, NY 10019
Phone: 212-523-6915
Fax:
E-mail: ylai@chpnet.org

MSSM Additional Monitor:

Last Name: Pai B.H
First Name: Poonam
Academic Title: Research Personnel, Physician
Department: Anesthesiology
Mailing Address: Mount Sinai West 1000 10th Avenue, New York, NY 10019
Phone: 212-523-6915
Fax:

E-mail: phebbalasankatte@chpnet.org

The principal monitor is a board certified anesthesiologist thus minimizing the risk to the subjects and further optimizing their health and wellbeing. Adverse events will be monitored as a standard of care everyone receives regardless of participation in the study. The safety and data information will be reviewed on a daily basis until the desired sample size is achieved. All temporary and/or permanent suspensions will be reported.

j)Withdrawal of Subjects

Patients may withdraw from the study at any given time by contacting any member of the research study group. Data will not be collected on patients who wish to withdraw. Patient do not need to withdraw consent in writing.

6)Risks to Subjects

If patients are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to the patient or their insurance in the ordinary manner and the patient will be responsible for all treatment costs not covered insurance, including deductibles, co-payments and coinsurance. This does not prevent the patient from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

As with any medication, there is a possibility of an allergic reaction. Although rare, possible complications include LA toxicity, hypersensitivity reaction, bleeding or local site infection, chance of pneumothorax. All anesthesiologists involved in patient care will be prepared for the prevention and rescue for any complications involving local anesthetic injections.

7)Provisions for Research Related Harm/Injury

If patients are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to the patient or their insurance in the ordinary manner and the patient will be responsible for all treatment costs not covered insurance, including deductibles, co-payments and coinsurance. This does not prevent the

patient from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

8)Potential Benefits to Subjects

It is important to know that patients may not get any benefit from taking part in this research. However, possible benefits may be improved knowledge about how the different forms of analgesia affect pain control in thoracic surgery. There is potential for better pain control for the surgery.

9)Provisions to Protect the Privacy Interests of Subjects

Patients will be appropriately educated about the research study. Any questions or concerns they have will be adequately addressed and patients will have the option to decline participation. Patients will be given as much time as they need to review the consent form. The study personnel will be approaching the subjects. Privacy will be maintained by not including any identifiers such as names or addresses in the data collected.

The identities of human subjects whose data is being studied will be de-identified as per HIPAA Privacy Rule.

10)Economic Impact on Subjects

Patients will not incur any additional cost for participating in the study. The medications used are part of a standard anesthetic regimen that will be billed to subject's insurance as bundled standard of anesthesia care. The cost of the procedure is overall unaffected.

11)Payments to Subjects

Patients will not be reimbursed for their participation.

12)Consent Process

Informed consent will be obtained prior to the procedure. Both the HRP-090 (SOP) Informed Consent Process for Research and the HRP-091 (SOP) Written Documentation of Consent will be followed by the study team. These documents are both available at http://icahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects/irb-members-palette.

13)Process to Document Consent in Writing

The patients will receive a paper copy of the IRB approved consent packet and will sign in the designated areas to confirm consent of participation. They will have the option of have a copy of the consent and may ask for a personal copy of the consent.

14)Vulnerable Populations

Indicate specifically whether you will include (target) or exclude each of the following populations:

Include	*Exclude*	*Vulnerable Population Type*
	X	*Adults unable to consent*
	X	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	X	*Wards of the State (e.g. foster children)*
	X	*Pregnant women*
	X	*Prisoners*

15)Multi-Site Human Research (Coordinating Center)

This study will be performed within the Mount Sinai West Hospitals. No additional centers will be involved.

16)Community-Based Participatory Research

This does not apply to our study.

17)Sharing of Results with Subjects

Results will not be shared with the patients since the study will take time to complete. Patients can request results if they contact the PI by writing.

18)External IRB Review History

This does not apply to our study.

19)Control of Drugs, Biologics, or Devices

Not applicable. Local anesthetic are routinely used in this setting.