IRB Minimal Risk Protocol Template

Note: If this study establishes a human specimen repository (biobank) for research purposes, do not use this template. Use the Mayo Clinic Human Specimen Repository Protocol Template found on the IRB home page under Forms and Procedures at http://intranet.mayo.edu/charlie/irb/

First-time Use: Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this document to the protocol section.

Modification: To modify this document after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points , save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

General Study Information

Principal Investigator: Dr. John Stauffer

Co-investigators: Dr. Ryan Chadha, Dr. Steven Clendenen

Study Title: Paravertebral block vs no block in open pancreaticoduodenectomy: prospective randomized controlled trial
NCT05820997

Protocol version number and date: V1 11/2/2022, V3 1/17/2023

Research Question and Aims

Hypothesis: We hypothesize that patients undergoing open pancreaticoduodenectomy who receive a paravertebral block, will have less postoperative pain and a shorter length of stay than those who only receive no paravertebral block.

Aims, purpose, or objectives:

Compare intra and postoperative pain control between Paravertebral block vs no block in open pancreaticoduodenectomy. Length of stay, and complications will also be recorded.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):

Pancreaticoduodenectomy (PD) is the surgical procedure of choice for the resectable and the borderline pancreatic cancers as well as many other indications [1]. Much progress has been attained in order to improve outcomes, such as length of hospital stay, pain management, and complications after PD [2]. Postoperative pain is one of the most frequent complaints after open pancreaticoduodenectomy. For that reason, different surgical approaches have been implemented to decrease the intra and postoperative pain such as changing the skin incision from subcostal transverse to upper midline small incision, epidural catheter use, or even minimally invasive surgery. Multimodal analgesic techniques play an important role in this particular field.

The para vertebral block (PVB) is a regional anesthesia technique which is widely used in thoracic surgeries[3]. PVB has been described mainly for ipsilateral somatic and sympathetic nerve blockade in multiple contiguous dermatomes above and below the site of injection[4]. Most literatures show its efficacy in pain management for thoracic surgeries and more recently PVB has been recommended and used for a wide range of abdominal surgeries, such as inguinal hernia repair and appendectomy[5].

Although, thoracic PVB have been performed for abdominal procedures[6], there is no enough knowledge data about the effect of PVB on the outcome of complex abdominal surgeries, such as open PD [2, 7]. For that reason, we aim to compare intra and postoperative pain management between PVB versus no block in open PD.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol*.

Paravertebral block is one of the standard of care options for postoperative pain management in patients with under going open pancreaticoduodenectomy.

Patients scheduled for surgery will be randomized into two groups through simple open randomization. Randomization and data capture will be done using the REDCap system. Patients in group A, will receive a paravertebral block, administered preoperatively, which is standard of care. Those in group B will form a control group receiving no paravertebral block, which is standard of care. For the Paravertebral Block group; patients will receive an ultrasound guided paravertebral at the T7-10 levels bilaterally with 5 cc of .5% ropivacaine at each level. The ropivacaine is given as a local anesthetic. Intraoperative analgesic management will be at the discretion of the anesthesiologist. Currently receiving the block pre-procedure is standard of care and not receiving the block is standard of care and given based on physician assessment. For this study we would plan to randomize to obtain objective data for clinical decisions and improve patient outcomes between the two standard of care groups. Patients would normally be in one or the other group even if they do not participate in the study. With the randomization we hope to obtain more objective data regarding patient outcomes.

Following surgery patients in both groups, we will collect data from the first 48 hours after surgery and at discharge. Patients will not be required to come into the clinic for any extra visits, there will be no questionnaires.

Study design: Prospective, Randomized Trial

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Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 40

Subject population (children, adults, groups): Adults

Inclusion Criteria:
-Patients willing and have signed consent.
-Nonpregnant adults undergoing open pancreaticoduodenectomy via standard upper midline incision without contraindications to PVB

Exclusion Criteria:
-Not able or unwilling to sign consent.
-Currently pregnant or lactating.
-Patients with chronic pain, requiring daily opiate use at time of surgery.
-Patients intolerant of opiates, NSAIDS, acetaminophen or local anesthetics.

Biospecimens

Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

Prospective collection of biological specimens other than blood: _____

Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

Date Range for Specimens and/or Review of Medical Records:
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

☒ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement:
The primary endpoint is postop pain visual analog scale. With pain scale ranging from 0 to 10, the standard deviation is estimated to be 2.5, based on two-sample t test, 20 patients per group (40 in total) will allow us to detect a mean difference of 2 points or larger in postop pain scale, with 0.05 significance level and 80% power.

Data Analysis Plan:
Patients demographic and baseline characteristics will be summarized as mean (SD) or median (range) for continuous variables and frequency (%) for categorical variables. Standardized mean difference will be calculated to indicate the size of the difference between the randomized groups. Postop outcome variables will be reported as mean (SD) or median (range) for continuous variables and frequency (%) for categorical variables. Two-sample t test will Wilcoxon rank sum test will be used to compare continuous variables between the two groups and chi-squared test or Fisher's exact test will be carried out to compare the categorical variables. All tests will be two-sided, with p value<0.05 considered statistically significant.

Endpoints
Primary:
Intra and postoperative pain medications consumption
Mean pain score initial 48 hrs postop
Length of stay
Return of bowel function
Secondary: Postop complications

References:

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