Identifiers: NCT02056301 **Unique Protocol ID**: H31096

Title: A Comparison Trial Between PCA and Epidural Analgesia for Pectus Excavatum Repair

Date: 24 April 2019

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-31096
Status: Approved
Initial Submit Date: 5/29/2012
Approval Period: 4/24/2019 - 4/23/2020

Section Aa: Title & PI

A1. Main Title

A COMPARISON TRIAL BETWEEN PATIENT CONTROLLED INTRAVENOUS ANALGESIA AND EPIDURAL ANALGESIA FOR PECTUS EXCAVATUM REPAIR

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

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A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:

TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

A9. ClinicalTrails.gov Registration

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Pectus excavatum is a cartilaginous deformity that is the most common congenital anterior chest wall defect in children [1]. Children with this disease process often complain of dyspnea, decreased exercise tolerance, and shortness of breath implying a restrictive pulmonary deficit [2]. Besides the reported physical limitations, patients can also exhibit manifestations of psychological disturbances (poor body image and depression). Surgical repair has been correlated with enhanced quality of life and improvement in body image[3] with recent studies showing improved pulmonary function and cardiac output [4, 5]. Surgery initially introduced by Sauerbruch involved rib cartilage resection and sternal osteotomy. This open procedure was further modified and became [6] known as the Ravitch procedure. This was the mainstay for repair for over 40 years until the introduction of minimally invasive surgery without rib resection by Nuss and colleagues in 1987 [7]. The Nuss repair involves placing an intrathoracic brace through small lateral chest wall incisions aided by thoracoscopy. Similar to bracing the teeth, the Nuss procedure avoids osteotomy or rib cartilage resection [8]. The Nuss procedure is the most common minimally invasive procedure in use today to correct this condition and is the current standard of surgical practice. Complications from Nuss repair can range anywhere from 7% to 25% [9] and can occur for as long as the bar is in place. Pain control remains a major issue in the perioperative period as patients may require weeks to months of oral narcotics before becoming pain-free after correction of the pectus. A prospective multicenter study reported peak pain scores of 8 on a 0-10 scale in the postoperative period and a mean score of 3 at discharge [4]. Postoperative pain after pectus repair has been managed with IV opioids administered by patient controlled analgesia (PCA) devices and by thoracic epidural infusions of combinations of local anesthetics and opioids. It is unclear from published data which method is superior and different tertiary care centers in the USA have a preference for different methods.

Most of the published studies describing the experience at different centers were retrospective, had small number of patients and did not standardize postoperative care. Soliman noted pain scores were initially higher in the Post Anesthetic Care Unit in the epidural group, but subsequent scores were lower. In one center there was a 35% failure rate of epidural analgesia in the first 24 hours, leading this surgical group to question the value of attempting epidural analgesia. Different results have also been noted in prospective studies. Butkovic reported that intravenous patient controlled analgesia (PCA) with fentanyl was as effective as epidural infusions in controlling pain after pectus repair. These authors recommended avoidance of epidural infusions because of a high failure rate in their hands and because of the potential for neurological complications [10]. In contrast, Weber et al noted pain scores on a visual analog scale were lower in the epidural group compared to those randomized to morphine PCA and recommended epidural analgesia [11]. In a more recent randomized controlled trial, there was a longer operating room time, increase in calls to anesthesia, and greater hospital charges with epidural analgesia after repair of pectus excavatum. Pain scores were lower in the epidural group early in the postoperative course and patient-controlled analgesia during the later part of hospital stay. [12] However, their results were confounded by a high failure rate (22%) in the placement and maintenance of thoracic epidural catheters. In addition, the age distribution of subjects differed with younger

patients in the IV PCA group. It is well established that younger subjects have less pain than older children after this operation. There remains a need for a randomized controlled trial to determine which method of analgesia is better in this patient population.

1. Kelly, R.E., Jr., et al., Pectus excavatum in a 112-year autopsy series: anatomic findings and the effect on survival. J Pediatr Surg, 2005. 40(8): p. 1275-8. 2. Nuss, D. and R.E. Kelly, Jr., Indications and technique of nuss procedure for pectus excavatum. Thorac Surg Clin, 2010. 20(4): p. 583-97. 3. Krasopoulos, G., et al., Nuss procedure improves the quality of life in young male adults with pectus excavatum deformity. Eur J Cardiothorac Surg, 2006. 29(1): p. 1-5. 4. Kelly, R.E., Jr., et al., Prospective multicenter study of surgical correction of pectus excavatum: design, perioperative complications, pain, and baseline pulmonary function facilitated by internet-based data collection. J Am Coll Surg, 2007. 205(2): p. 205-16. 5. Malek, M.H., et al., Cardiovascular function following surgical repair of pectus excavatum: a metaanalysis. Chest 2006. 130(2): p. 506-16. 6. Ravitch, M.M., The operative treatment of pectus excavatum. J Pediatr, 1956. 48(4): p. 465-72. 7. Nuss, D., et al., A 10-year review of a minimally invasive technique for the correction of pectus excavatum. J Pediatr Surg, 1998. 33(4): p. 545-52. 8. Nuss, D. and R.E. Kelly, Jr., Minimally invasive surgical correction of chest wall deformities in children (Nuss procedure). Adv Pediatr, 2008. 55: p. 395-410. 9. Densmore, J.C., et al., Initial surgical and pain management outcomes after Nuss procedure. J Pediatr Surg, 2010. 45(9): p. 1767-71. 10. Butkovic, D., et al., Postoperative analgesia with intravenous fentanyl PCA vs epidural block after thoracoscopic pectus excavatum repair in children. Br J Anaesth 2007. 98(5): p. 677-81. 11. Weber, T., et al., Superior postoperative pain relief with thoracic epidural analgesia versus intravenous patient-controlled analgesia after minimally invasive pectus excavatum repair. J Thorac Cardiovasc Surg, 2007. 134(4): p. 865-70. 12. St. Peter, S.D., et al., Epidural vs patient-controlled analgesia for postoperative pain after pectus excavatum repair: a prospective, randomized trial. Journal of Pediatric Surgery, 2012. 47(1): p. 148-153.

Section D: Purpose and Objectives

The aim of this study is to compare the efficacy of epidural and IV analgesia in controlling pain in patients undergoing Nuss repair of pectus excavatum. The primary end point will be the difference in pain scores at rest and with activity (coughing, deep breathing and movement) during postoperative days 1 -5.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 2: Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Child (3-12 yrs)

Ethnicity:

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Subjects/parents/guardians will be approached in the waiting area on the day of surgery prior to the start of the procedure. The study will be verbally explained with emphasis on the voluntary nature of study participation. A written consent form will be provided with ample time given to consider the study. A translator will be available for Spanish speakers and a Spanish Short form will be used for these subjects. . Participants will be assured that every effort will be made to protect privacy and to prevent a breach of confidentiality.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

y) Drug, Phase IV, Single Center

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This patient blinded prospective randomized single blind (patient) study will be performed on patients (ages 8-18 years, both males and females, from all ethnic backgrounds) undergoing minimally invasive pectus excavatum repair at the Texas Children¿s Hospital, Houston, Texas. After obtaining IRB (Institutional Review Board) approval and written informed consent from each patient or his or her legal representative, 64 patients scheduled for thoracoscopic repair of pectus excavatum will be randomly assigned into two treatment groups based on a computer generated random number using Random Allocation Software For Parallel Group Randomized Trials. There are 2 treatment arms in this study. There are no control or placebo groups and there is an equal chance of being assigned to either group. One group will have a patient controlled device connected to an intravenous patient controlled analgesia (IV PCA). This device runs a basal infusion of pain medicine (morphine) intravenously with additional allowable patient controlled doses every 10 minutes. The other group will have an epidural catheter inserted under sterile conditions in the thoracic epidural space after anesthesia has been induced. This will be connected to a patient controlled epidural analgesia (PCEA) device for postoperative pain control that works in a similar manner except the medication (a combination of local anesthetics and hydromorphone) will be administered in the thoracic epidural space. The patients will be blinded to the treatment arm. The epidural catheter will be placed after induction of anesthesia in the thoracic epidural group by the Pain Service Attending Anesthesiologist, who is a different person from the anesthesiologist in the room. The Pain Service Attending Anesthesiologist has the most experience in pacing these catheters. In the IV PCA group, a catheter will be taped to the outside of the skin in the same fashion as the thoracic epidural catheter but without any needles being used. The anesthesiologist caring for the patient during surgery will not be blinded. They will care for the patient based on their clinical judgment. However, it will not be possible to blind the nurses taking care of the patient after surgery as different medications, infusion rates and programs for limiting drug use are used in the PCA and PCEA devices.

Inclusion Criteria:

1) Patients age 8- 18 years 2) Patients undergoing minimally invasive pectus excavatum repair via Nuss procedure 3) American Society of Anesthesiology Status I-III

Exclusion Criteria:

1) Refusal of epidural catheter 2) Pregnancy 3) Bleeding History 4) Inability to understand how to use the PCA device 5) Medication interfering with blood coagulation 6) Patients allergic to local anesthetics 7) Patient refusal to participate in study 8) Developmental delay

F2. Procedure

The perioperative management of patients will be in keeping with the current standard practices at the Texas Children¿s Hospital. All subjects will be asked to assess their baseline pain on a 0-10 verbal rating scale. All subjects will be told that they will be provided with a device in the postoperative period that will allow them to receive additional pain medications when they press a button. They will be told to press the button whenever they need pain medications. Patients will be informed that if they do not get enough relief of pain after pressing the button, they should inform their nurse who will give additional drugs as required. Prior to the induction of general anesthesia, all patients will be premedicated with diazepam 0.15 mg / kg body weight (max dose 10 mg) orally. Anesthesia will be induced via mask inhalational anesthesia with oxygen, nitrous, and sevoflurane or with IV propofol 2 mg/kg in keeping with the preferences of the patient and the Attending Anesthesiologist. After placement of intravenous access, rocuronium 0.6 mg / kg and fentanyl 2 mcg/ kg will be administered, the trachea intubated, and anesthesia maintained with desflurane at an end tidal concentration of 6.6 % or minimum alveolar concentration (MAC)adjusted to keep heart rate and blood pressure within 20% of baseline values. All patients will receive a loading bolus of 10 ml / kg of isotonic Lactated Ringer¿s solution. An opaque envelope containing the group assignment will be opened after induction of anesthesia. Patients assigned to the IV - PCA group will have an epidural catheter taped to the skin of the patient¿s back without any needles being inserted. Patients assigned to the thoracic epidural group (PCEA) group will have a thoracic epidural catheter (Arrow Epidural Catheter Kit) placed with a 18 gauge Tuohy needle inserted in the T5-6 or T6-7 inter-vertebral space using a loss of resistance to normal saline in the lateral position. In keeping with standard practice at the TCH, the position of the thoracic epidural catheter tip will be confirmed by real time fluoroscopy and a single injection of 1 ml of omnipaque 180 mg/mL contrast. In keeping with current practice, a bolus of 0.2% ropivacaine 0.3 ml per kg (maximum dose 20 ml) will be administered in the epidural space to the patients in the TEA group at least 10 minutes prior to surgical incision.

The patients in both groups will receive additional boluses of fentanyl and rocuronium as clinically indicated according to the judgment of the Attending Anesthesiologist. At the end of the surgical procedure, residual neuromuscular blockade will be antagonized and the trachea extubated in the operating room when the Attending Anesthesiologist decides it is safe to do so. The patient will then be transferred to the post anesthesia recovery room (PACU).

Postoperative Analgesia All groups: In keeping with current practice, supplemental oxygen will be available for oxygen saturations less the 94% during spontaneous ventilation. All patients will be monitored with full cardiac ¿respiratory monitors. PCEA group: Analgesia will be maintained with an epidural infusion of 0.15% ropivacaine with hydromorphone 10mcg/ml at a rate of 0.2 ml / kg/ hour. This will be adjusted via our current practice to ensure adequate coverage of the surgical incision site. The epidural infusions device will be programmed to give additional patient controlled bolus doses of 1.5 ml with a lockout of 30 minutes. These are standard settings for children undergoing this procedure at the TCH. In keeping with current practices, the thoracic epidural catheter will be removed on the 4th POD. IV PCA group: Patients will receive a continuous infusion of morphine 0.02 mg/kg/hour IV. The infusion device will be programmed to allow additional patient controlled doses of morphine, 0.02 mg / kg morphine IV with a lockout time of 10 minutes and calculated 4 hour maximum dosing based on patient weight. This is in keeping with our current practice at Texas Children's Hospital for IV PCA. On the second postoperative day, the continuous infusion of morphine will be stopped, but PCA bolus doses continued in keeping with current practices to reduce opioid induced hyperalgesia and potential for respiratory depression. The epidural catheter that is affixed to the skin will have tubing attached to a device to continue blinding of the patient.

Protocol for breakthrough pain (both groups): If pain control is not adequate as judged by the patient, they will receive an additional 0.05 mg / kg bolus of IV morphine with reevaluation at 15 minutes. A second dose of morphine will be given if the pain scores remain above 4. If the patient continues to have pain, the protocol permits administration of any other drug necessary for pain relief as judged necessary by the Pain Service Attending. Transition to oral analgesics: Both groups will receive ketorolac 0.5 mg/kg IV q6hours for a total of 20 doses at POD #5. At the end of the 20 doses, this will be changed to Ibuprofen 400 mg orally every 6 hours. On the morning of the 4th postoperative day, patients will receive an oral combination of hydrocodone 7.5 mg/acetaminophen 325 mg tablets every 4 hours for 24 hours in keeping with current standard practices. In order to minimize total doses of acetaminophen to below 75 mg/kg/day, patients weighing less than 55 kg will receive 1 tablet. Patients between 55 and 80 kg will receive 1.5 tablets, and patients greater than 80 kg will receive 2 tablets. Postoperative Pain Assessment: The intensity of the pain will be assessed at intervals of 4, 8, 12, 16, 20, 24, 36, 48, 60, 72, 84, 96 hours using a 10 point numerical rating scale during rest and at ambulation. Pain scores will be measured at rest and after deep breathing or coughing. These scores are routinely gathered at these time points by nurses. The total number of analgesic doses that were demanded and administered doses will be recorded as well for both treatment arms along with the total dose of rescue morphine required during hospitalization.

The level of sedation will be determined using the University of Michigan Sedation Scale. Incidence of side effects like nausea, vomiting, pruritis, and urinary retention will be documented through hospitalization. On the afternoon of the 4th day, the epidural catheters and epidural pumps will be removed from the patient. At thsi

time point patients will have received 1-2 doses of oral analgesics. Patients will have an option of using the PCA morphine for severe breakthrough pain. The total amount of rescue morphine boluses and via the PCA pump required during the transition period will be documented. Patient and Parent Satisfaction Survey: All parents and patients will complete rate their satisfaction with pain control and their overall experience on a 0-10 scale daily for POD 1-5. These surveys will be collected daily by the research staff.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 84 Worldwide: 84

Please indicate why you chose the sample size proposed:

The primary endpoint of the study is the mean pain score. In a previous IRB approved retrospective study, the SD of pain scores in patients undergoing this procedure was 2.3. A difference of 2.0 in the raw pain scores is considered of clinical importance (Farrar: J Pain Symptom Manage 2003;25:406¿411). With a sample size of 58 in the intent to treat population randomized in a 1: 1 ratio, there is a 90% probability that the study will detect a treatment difference at a two-sided 0.05 significance level, if the true difference between treatments is 2.0 units. This is based on the assumption that the standard deviation of the response variable is 2.3. We plan to recruit 84 patients to allow for a drop out rate of 10%.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Summary data will be calculated for each group and examined for normal distribution using the Shapiro -Wilks test. The outcome variables between the groups will be compared with Student¿s t-test where appropriate, for normally distributed continuous data or by nonparametric tests (Mann Whitney test) if the data are not normally distributed. Categorical data will be compared by Fisher¿s exact test. Analysis of variance for repeated measures will be performed to compare differences in pain scores between the two treatment groups with time. Main effects and interaction between factors will be analyzed by one-way within subject¿s analysis of variance (ANOVA) and by two-way mixed ANOVA in repeated measures model. Sphericity assumption will be tested by Mauchly¿s test. Greenhouse¿ Geisser correction to the degrees of freedom and P-value will be applied if no or mild violation of sphericity is present. If the violation is stronger, the more conservative Huynh¿Feldt correction will be used. Data will be presented as mean ± SD, or numbers (percentages). P values less than 0.05 will be considered statistically significant.

The primary end point will be the mean pain scores at rest and with activity (deep breathing, coughing and movement) during postoperative days 1 -5. Secondary end points will include: a. Total usage of morphine in mg/kg for postoperative days (POD) 1-5. b. Number of demand doses for PCA/PCEA in the recovery period. c. Number of rescue analgesia doses on POD 1-5. d. Change in pain scores (delta P) during transition to oral medications between the 2 groups. e. Side effect incidence of nausea and vomiting, pruritus, urinary retention (requiring urinary catheterization), and respiratory depression f. Sedation as measured via the University of Michigan Sedation Scale g. Parental satisfaction and patient satisfaction scores h. Length of stay / time to discharge In addition to these we will caculate the raw difference in pain intensity (PID; 0¿10 numeric rating scale [NRS]), percentage difference in pain intensity (%PID; 0¿100% of the NRS), sum of the absolute difference pain intensity (SPID; sum of PID measurements divided by number of scores), percent of the maximum total pain relief (%Max TOTPAR). These are standard derived values in pain studies.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

In this study, we are comparing two techniques, which are currently used in our daily practice at TCH, for postoperative pain management after minimally invasive thoracoscopic repair of a pectus deformity. No patient will be receiving general anesthesia, local anesthetic infusion via an epidural and/or postoperative opioids solely for the purposes of the study, but as part of their routine care. There is no placebo or control group.

Patients who do not participate in this study will also require general anesthesia. Postoperative nausea and vomiting can also occur due to IV opioids (IV PCA group) used intraoperatively and postoperatively. Other side effects commonly seen with opioids can include respiratory depression, urinary retention, and constipation. The dose of opioids used in the study is not different from our current standard practice at TCH. It is possible that patients with effective analgesia from regional anesthesia may have better pain control and require less opioid in the postoperative period and may have less side effects from opioids. These patients (in the epidural group) may have more pain when the epidural infusion is stopped.

The risks of epidural placement include local anesthetic toxicity, intravascular injection of local anesthetic agent, and permanent neurologic injury. Other rare complications can include a high spinal (wet tap), infection, and bleeding into the epidural space from traumatic placement. It is quite rare for serious cardiac and neurologic complications to occur with regional anesthesia; and as such these complications are usually seen in the literature as case reports. 2 prospective French studies put this risk at 1.5 occurences per 10000 cases. Strict asepsis with full barrier precautions is used for placement of an epidural. Placement of the epidural occurs under general anesthesia to decrease trauma related to placement. This is considered the standard of care with pediatric patients. Bupivacaine has been routinely used for more than 25 years in pediatric patients. The upper limits of the dose to be used in this patient population is well established and available in standard textbooks of pediatrics (Behrman). The amount of local anesthetic used in our study group is less than 0.3 mg/kg, which is about 10% of the widely accepted maximum dose of the local anesthetic (bupivacaine 3 mg/kg) (Cote and Behrman). Serious side effects of local anesthetic toxicity from intravascular injectlon or absorption of local anesthetic agent include heart rate and rhythm changes, low blood pressure, seizure activity, brain damage and even death. Standard treatment for local anesthetic toxicity includes 20% intra lipid 1 ml/kg and if required cardiopulmonary resuscitation. The epidural solution is commonly a mix of local anesthetic and an opioid. Although the dose of the opioid is about 1/10 the intravenous dose, risks discussed earlier related to opioid exposure can manifest with this small dose in the epidural space as well.

Additional risks of the study are the small chance of loss of privacy. The data will be coded. No data identifying the patient will be extracted from the medical records and all data will be kept locked in the offices of the Principal Investigator. Any electronic version will be kept in a password protected network servers controlled by the IT services at the TCH. Computers with access to this network are kept in a locked office where entry is limited to those with an ID key card. This office is located inside the office of the Department of Anesthesiology at Texas Children's Hospital. Unauthorized individuals would not be able to enter these facilities. The likelihood of such events is minimal.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?
Yes

NOTE: The answer to the questions in H2 requires the completion of the form: 'Section H – Data and Safety Monitoring Plan' as an attachment in Section S.

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?
No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?
No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

If a patient is assigned to the thoracic epidural (PCEA) group, and if the thoracic epidural analgesia reduces postoperative pain and the need for postoperative opioids, the child may benefit from less pain and less side effects from opioids postoperatively. However, it is possible that there will be no benefits from participating in the study.

Describe potential benefit(s) to society of the planned work.

Data from this study can be used to determine if thoracic epidural or IV PCA provides better pain relief in patients undergoing the Nuss procedure for pectus repair. Society may benefit from this knowledge as it will permit other anesthesiologists to use the better technique in the future.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The risks in this study do not vary from the risks of standard practices at TCH for children undergoing thoracoscopic Nuss bar placement under general anesthesia with IV PCA or general anesthesia with PCEA. The additional minor risk of an unlikely loss of privacy is outweighed by the societal benefits from this knowledge.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Patients presenting for pectus repair will be identified from the Texas Children¿s Hospital operating room schedule that is routinely available to pediatric anesthesiologists. This will be cross referenced with the pediatric surgeons operative schedule as these cases are scheduled weeks to months in advance. Potential subjects will be approached about participation on their visit to our preoperative screening clinic. Voluntary participation will be emphasized during recruitment of patients. A copy of the IRB approved written consent form will be given to parents with time allowed to read and consider enrollment. All questions will be fully answered and another opportunity to raise questions will be presented on the day of surgery in the holding area.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

A full-length informed consent document
Short-Form consent documents

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

At what institution will the physical research data be kept?
Texas Children's Hospital

How will such physical research data be secured?
All data will be coded and the key to the code kept in a separate file from the collected data. The key to the code will be deleted/destroyed after the completion of the study. Physical data files will be kept in the locked offices of the Principal Investigator, with limited passkey/badge code access restricted. Physical data will also be maintained in the Anesthesia Dept. in a locked file cabinet with secured badge only access to main entry.

At what institution will the electronic research data be kept?
Electronic data will be stored in a password protected network controlled by the Texas Children's Hospital IT Dept.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
No

Such electronic research data will be secured via Other:

Yes, (describe below):
Texas Children's secured server of password only protected access controlled by the Texas Children's IT Dept.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

No research data related to and including PHI, sensitive and non-sensitive data will be shared with a sponsor. When collaborators need to access electronic data, they will log onto the TCH network servers using their TCH IT issued passwords.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Study findings may be published at professional meetings and/or peer reviewed journals. No data identifying an individual patient will be included in any report of the study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

Patient will be responsible for costs of anesthesia and analgesia, which can include epidural anesthesia regardless of study enrollment. There is no additional cost to the patient for participation in the study.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

Yes

If yes, be sure that you justify the use of the placebo for this research in the space below.

The placebo is actually an infusion device attached to te patient so they are unawre of which treatment arm they are in. No placebo is actually given or infused into the patient.

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

None