Identifiers: NCT02206685 **Unique Protocol ID**: H32894

Title: A Trial Comparing Single Intra-op Dose of Methadone Versus Placebo in Patients Undergoing Spine Surgery

Date: 28 January 2020

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-32894
Status: Approved
Initial Submit Date: 4/16/2013
Approval Period: 1/28/2020 - 1/27/2021

Section Aa: Title & PI

A1. Main Title

A RANDOMIZED BLINDED PROSPECTIVE TRIAL COMPARING SINGLE INTRAOPERATIVE DOSE OF METHADONE VERSUS PLACEBO IN PEDIATRIC PATIENTS UNDERGOING SPINE SURGERY

A2. Principal Investigator

Name:	KIM-PHUONG NGUYEN	Phone:	832-824-5809
Id:	134207	Fax:	832-825-5801
Department:	ANESTHESIOLOGY: BCM	Email:	ktn@bcm.tmc.edu
Center:		Mail Stn:	BCM120

A3. Administrative Contact

Name:	MARGARET OWENS-STUBERFIELD	Phone:	832-824-5800
Id:	193093	Fax:	
		Email:	owensstu@bcm.tmc.edu
		Mail Stn:	BCM320

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

A4. Co-Investigators

Name:	FRANK GEROW	Phone:	832-822-3100
Id:	024989	Fax:	832-825-3127
Department:	ORTHOPEDIC SURGERY	Email:	fgerow@bcm.tmc.edu
Center:		Mail Stn:	BCM616
Name:	DARRELL SCOTT HANSON	Phone:	713-986-5750
Id:	030922	Fax:	713-986-5751
Department:	ORTHOPEDIC SURGERY	Email:	dhanson@bcm.tmc.edu
Center:		Mail Stn:	BCM616
Name:	NIHAR PATEL	Phone:	832-824-5800
Id:	039846	Fax:	
Department:	TCH ANESTHESIOLOGY	Email:	nvp1@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	WILLIAM PHILLIPS	Phone:	832-822-3100

Id:	125846	Fax:	832-825-3127
Department:	ORTHOPEDIC SURGERY	Email:	williamp@bcm.tmc.edu
Center:		Mail Stn:	BCM615
Name:	EDDIE MEDELLIN JR	Phone:	832-824-5866
Id:	174073	Fax:	
Department:	TCH ANESTHESIOLOGY	Email:	emedelli@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	SARAH LAQUA	Phone:	832-824-5800
Id:	177144	Fax:	
Department:	TCH ANESTHESIOLOGY	Email:	endique@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	ANDREW LEE	Phone:	832-822-0761
Id:	194763	Fax:	
Department:	TCH ANESTHESIOLOGY	Email:	adlee@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	CHRIS GLOVER	Phone:	832-824-5800
Id:	691844	Fax:	
Department:	TCH ANESTHESIOLOGY	Email:	cdglover@bcm.tmc.edu
Center:		Mail Stn:	BCM320
Name:	HILLARY CLOYD	Phone:	8328220753
Id:	Non-Baylor	Fax:	
Institution:	Texas Children's Hospital	Email:	hocloyd@texaschildrens.org
Address:			

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?
No

A9. ClinicalTrails.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,

- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT02206685

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Scoliosis is a disease that involves lateral and/or rotational deformity of the spine and can affect up to 4% of the population. Typically, surgery is considered when Cobb's angle, which is a measurement used for evaluation of curves in scoliosis on an anterior-posterior radiographic projection of the spine, is greater than 50 degrees in the thoracic region (40 degrees in the lumbar region) or when the curvature causes significant pain, or respiratory and cardiovascular restriction. Patient undergoing this surgical correction experience severe pain in the postoperative period and the management includes the use of opioid-based patient-controlled analgesia (PCA).

Methadone is an opioid with one of the longest elimination half-life and has been used as an effective analgesic for acute, chronic, neuropathic, and cancer pain in adults, children, and even neonates1-5. Its long duration of action and antagonism to the N-methyl-d-aspartate receptor may decrease the need for PCA use in the postoperative period. Gourlay2 demonstrated the effectiveness and utility of perioperative methadone including the advantages of longer analgesia with no serious side effects of respiratory depression. A recent study by Gottschalk2 in adult patients demonstrated a 50% reduction of postoperative opioids at 48 hours and lower pain scores after a single bolus of methadone before surgical incision. However, a major weakness of the study is that patients did not receive equipotent intraoperative opioids. In addition, the adolescent patient population will undergo a much larger surgical incision with potential for greater postoperative pain. Despite this potential benefit, methadone is seldom used in the perioperative setting. A more recent pharmacokinetic study of methadone in adolescents undergoing spine surgery failed to show a reduction in opioid consumption as it was powered to determine pharmacokinetics and not a secondary endpoint of postoperative opioid consumption. An appropriately powered study is still required to determine the efficacy of methadone in reducing postoperative pain after spine surgery.

1. Nicholson AB. Methadone for cancer pain. Cochrane Database Syst Rev 2007:CD003971 2.Gourlay GK et al. Pharmacodynamics and pharmacokinetics of methadone during perioperative period. Anesthesiology 1982; 57:458-67. 3. Gottschalk A et al. Intraoperative methadone improves postoperative pain control in patients undergoing complex spine surgery. Anesth Analg 2011; 112:218-23. 4. Sharma A, Tallchief D, Blood J, Kim T, London A, Kharasch ED: Perioperative pharmacokinetics of methadone in adolescents. Anesthesiology 2011; 115:1153¿ 61. 5. Berde CB, Beyer JE, Bournaki MC, Levin CR, Sethna NF: Comparison of morphine and methadone for prevention of postoperative pain in 3- to 7-year-old children. J Pediatr 1991; 119:136 ¿ 41

Section D: Purpose and Objectives

The aim of this study is to explore the efficacy of a single intra-operative dose of methadone in patients with idiopathic scoliosis undergoing multi-level posterior instrumentation and spinal fusion. The primary endpoints is the total opioid usage during POD (postoperative day) 0-4. Secondary endpoints include and pain scores during rest and with activity (getting out bed and ambulation) on POD 0-5 and side effects of pain medications

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:
All Ethnicities

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?

Patients presenting for spinal surgery 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 orthopedic surgeons' operative schedule as these cases are scheduled weeks to months in advance. The chart is reviewed to insure that the patient qualifies based on the inclusion and exclusion criteria.

Potential subjects will be approached about participation on their visit to our preoperative screening clinic which occurs a few days prior to surgery. The child will be approached with parental presence during the preoperative screening visit and age appropriate language will be used to explain the study and answer any questions. Every opportunity will be given to answering questions and discussing their options throughout the study. Enrollment in the study will only occur if the child assents and the parent consent. 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 for reading and considering enrollment. Another opportunity to raise questions will be presented on the day of surgery in the holding area. All questions will be fully answered and the child will then be asked to sign their name on the assent portion with parent or guardian signing the IRB approved consent. A translator will be available for Spanish speakers and a fully translated consent form approved by the IRB will be used for these subjects. (A Spanish consent will be submitted as an amendment after the English consent is approved. No Spanish speakers will be recruited for enrollment prior to IRB approval of a Spanish translation of the consent form.) 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 and observer blinded prospective randomized study will be performed on patients (aged 10 - 17years, both males and females, from all ethnic backgrounds) undergoing multilevel thoraco-lumbar spine surgery with instrumentation and fusion at Texas Children¿s Hospital, Houston, TX. After obtaining IRB (Institutional Review Board) approval and written informed consent from each patient or his or her legal representative, 56 patients scheduled for multilevel thoraco-lumbar spine surgery with instrumentation and fusion will randomly be assigned into two groups (control or treatment group) based on a computer generated random number using Random Allocation Software For Parallel Group Randomized Trials. There is an equal chance of being assigned to either group. The control group will be given placebo; whereas the treatment group will receive methadone 0.2 mg/kg intravenously.

Inclusion Criteria:

1) Patient age 10 ¿ 17 years 2) Patients undergoing multilevel thoraco-lumbar spine surgery with instrumentation and fusion

Exclusion Criteria:

1) Preoperative methadone therapy 2) Inability to use the PCA 3) Allergy to methadone or morphine 4) Morbid obesity with a body mass index >36.0 kg/m2 5) Patients with chronic renal failure defined by serum creatinine >2.0 mg/dL 6) Liver failure defined as a history of cirrhosis or fulminant hepatic failure 7) Preoperative congenital heart disease or arrhythmias 8) Patient refusal to participate in study 9) Pregnancy (It is standard of care for all post menarche female patients to undergo a urine pregnancy test prior to surgery).

F2. Procedure

The perioperative management of patients will be in keeping with the current standard practices at Texas Children¿s Hospital. Before surgery, patients will be asked to rate their baseline pain using a verbal rating scale from 1 to 10 by a member of the research team. In addition, information on preoperative opioid consumption during the last 30 days will be collected.

Muscle spasms after scoliosis surgery are a common cause of postoperative pain. Our current practice is to provide oral or IV diazepam to treat muscle spasms. Many patients who undergo scoliosis repair receive pre-operatively oral diazepam or midazolam for anxiolysis. In order to prevent introducing a confounding factor in the evaluation of postoperative pain scores in the recovery period, the protocol will require all patients to receive the same preoperative medication (oral diazepam). After intravenous access, endotracheal intubation will be facilitated with additional bolus of propofol 1-3 mg/kg or succinylcholine 1-2 mg/kg at the discretion of the intra-operative anesthesiologist. According to the randomization plan, after intubation, the control group will receive a 20 ml normal saline placebo infusion over 10 minutes, while the treatment group will receive 0.2 mg/kg methadone diluted to a 20 ml infusion over 10 minutes. The inhalational agent will be turned off at intubation in keeping with standard TCH practices. Total intravenous anesthesia in both groups will be maintained in keeping with standard TCH practices for neuromonitoring (somatosensory evoked potentials (SSEPs) and motor evoked potentials (MEPs) with propofol 75 - 200 mcg/kg/min and sufentanil 0.2 ¿ 0.5 mcg/kg/hour, adjusting the doses to achieve a targeted bispectral index level of 40-60. Nicardipine infusion may be used for controlled hypotension at the discretion of the intra-operative anesthesiologist. The sufentanil and propofol infusion will be turned off when the second rod is placed and after the final SSEPs, MEPs are obtained. Anesthesia will be maintained with inhalational agent until the end of the surgical procedure. At the end of surgical procedure, residual neuromuscular blockade will be antagonized and the trachea extubated in the operating room when the Anesthesiologist decides it is safe. The patient will then be transferred to the post anesthesia recovery room (PACU). Both the intra-operative anesthesiologist and the researcher staff gathering the PACU pain scores and use of PCA will be blinded to the medication.

Postoperative Analgesia All groups: In keeping with current practice, supplemental oxygen will be available for oxygen saturations less than 94% during spontaneous ventilation. All patients will be monitored with continuous pulse oximetry as in keeping with practice at TCH. Every patient will have a patient controlled analgesia (PCA) morphine pump with a basal rate infusion of 0.01 mg/kg/hour, a demand dose 0.02 mg/kg with a lockout time of 10 minutes to be started in the PACU once the patient emerges from the anesthetic. The patient will be administered diazepam 0.05 mg/kg IV or oral with maximum of 5 mg every 6 hours as needed for muscle spasms in keeping with current practice. On POD 1, the basal rate of morphine will be discontinued and ketorolac 0.5 mg/kg every 6 hours initiated in keeping with current practices. On POD 3, the patient will be transitioned from the PCA with scheduled oral hydrocodone/acetaminophen at a dosage of 0.135 mg/kg of hydrocodone with a maximum of 15 mg every 4 hours in keeping with current practice. The PCA will be available for use during the transition for breakthrough pain.

Postoperatively, patients will be asked to rate their pain using a validated pain scale (a verbal rating scale where 0 = no pain and 10 = worse pain ever) by a blinded research staff member. These pain scores will be collected at 1 hour after entry into recovery and every 4 hours during the first five days of hospitalization both at rest and during activity by the nurses. The cumulative intravenous opioid requirement at 24, 48, and 72 hour will be recorded. The cumulative breakthrough intravenous opioid requirement after initiation of oral pain medication will also be collected. The level of sedation will be determined using the University of Michigan Sedation Scale. In addition, complications such as the incidence of hypotension (defined as mean arterial blood pressure less than 50 mm Hg), the need for vasopressors, the incidence of respiratory depression (defined as a respiratory rate less than 8 breaths per minute, respiratory arrest, or the need for naloxone), the incidence of hypoxemia or desaturation (defined as oxygen saturation [Sao2] less than 90% or the need for a supplemental oxygen to maintain Sao2 greater than 94%), the incidence of cardiac arrhythmias, and the incidence of nausea and vomiting including the treatment of side effects will be also recorded. Upon discharge from the hospital, the patients will be asked to keep a diary consisting of daily opioid usage, episodes of nausea and vomiting, daily activity level, and satisfation scores. As part of standard routine post-surgical followup in the orthopedic clinic, information is collected from the patients which consist of questionnaires regarding pain scores, functional status, activity level, and quality of life. The research team will collect this information at 3 months and 6 months postoperatively.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 98 Worldwide: 98

Please indicate why you chose the sample size proposed:

The sample size was based on the assumption that opioid use in the first 3 days in the placebo group would be similar to that in a previously published study of the same patient population undergoing spine surgery (mean 275 mg SD 75 mg). A group size of 28 would be required for an 80% power of detecting a 30% reduction in opioid use from 275 to 200 mg at the 0.05 level of significance. Allowing for a 50% dropout rate for incomplete data, we will recruit 49 patients in each group for a total of 98 subjects.

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?

The primary endpoint of the study is the morphine consumption during the first 72 postoperative hours. The secondary outcomes include pain scores and the incidence of side effects such as respiratory depression, nausea, and vomiting. Continuous data including pain scores will be first examined for a normal distribution by the Shapiro ¿ Wilk test. The outcome variables between the two groups will be compared with Student¿s t-test where appropriate, for normally distributed continuous data or by nonparametric tests if the data were not normally distributed. It is anticipated that the distribution of pain scores will not be normal and that non-parametric tests will be required. Categorical data including patient gender, ASA physical status, incidence of side effects (respiratory depression, need for oxygen beyond the first 2 hours, nausea and vomiting) 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 treatment groups with time. Data will be presented as mean, standard deviation, median values or numbers (percentages). P values less than 0.05 will be considered statistically significant. In order to maintain a robust statistical analysis, we will also examine the differences in subjects with and without completely evaluable data in known factors that affect postoperative pain after spine surgery (e.g., age, gender, ASA physical status, duration of surgery, intraoperative opioids medications, time of the PACU stay, mean and peak pain scores and recorded opioid consumption in the PACU before discharge). Failure to show a difference in these factors may suggest that the missing data can be considered to be missing at random.

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 the addition of another opioid pain medication to reduce pain scores and overall total hospital opioid consumption. Current standard practices for patients undergoing multi-level spine surgery will be used with the exception of methadone given to the treatment group. Methadone may induce prolongation of the rate-corrected QT interval (QTc); however, patients with cardiac arrhythmias or congenital heart disease will be excluded from the study. Side effects of respiratory depression from methadone should not be greater than with typical morphine usage.

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.

Patients assigned to the methadone group may have reduced postoperative pain scores and a reduction of total consumption of postoperative opioids. Patients with less opioid use may benefit from fewer side effects. 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 methadone provides better pain control in the perioperative setting. Knowledge obtained from this study may allow anesthesiologists from other institutions caring for children and adolescents undergoing similar painful procedures to use this medication to reduce pain.

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 multi-level thoraco-lumbar spinal instrumentation and fusion. 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 spinal surgery 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 orthopedic surgeons' operative schedule as these cases are scheduled weeks to months in advance. The chart is reviewed to insure that the patient qualifies based on the inclusion and exclusion criteria. The study staff will ask the surgeon if they may approach the patient and parents about the study.

Potential subjects will be approached about participation on their visit to our preoperative screening clinic which occurs a few days prior to surgery. The child will be approached with parental presence during the preoperative screening visit and age appropriate language will be used to explain the study and answer any questions. Every opportunity will be given to answering questions and discussing their options throughout the study. Enrollment in the study will only occur if the child assents and the parent consent. 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 for reading and considering enrollment. Another opportunity to raise questions will be presented on the day of surgery in the holding area. All questions will be fully answered and the child will then be asked to sign their name on the assent portion with parent signing consent . A copy of the signed consent form will be given to parents.

A TCH translator or a Spanish-speaking research staff will thoroughly explain the study to the child and the parent. After all questions are answered and the study staff is assured that the study is understood and participation is agreed, the child will sign their name on the assent portion parent signing consent. A copy of the consent will be given to the parent.

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

J3. Privacy and Intrusiveness

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

Yes

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?
PHI data is currently stored in a locked drawer in the PI's research office at the department of Anesthesiology located at Texas Children's Hospital. The entrance to the department is always locked and accessible only to research personnel using key cards and regularly patrolled by security every day.

At what institution will the electronic research data be kept?

All computerized electronic data is kept in a password protected network servers controlled by Information Technology services at Texas Children's Hospital. Computers with access to this network are located in the PI's research office where access is limited by personal ID card entry. Computers are locked and must be accessed with using personal password.

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 IT services with secured network servers. No portable devices are being used to store any data.

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 protected health information or data will be transmitted to any sponsors or collaborators.

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, 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.

An appropriately powered study is still required to determine the efficacy of methadone in reducing postoperative pain after spine sugery and must be compared against a placebo to obtain.

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