Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-40844
Status: Closed
Initial Submit Date: 5/4/2017

Section Aa: Title & PI

A1. Main Title

DOES USE OF ULTRASOUND REDUCE THE RATE OF SHAM CAUDAL BLOCK IN CHILDREN WHEN COMPARED TO BLIND TECHNIQUE

A2. Principal Investigator

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Section Ab: General Information

A4. Co-Investigators

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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?
Not set yet

A9. ClinicalTrails.gov Registration

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Caudal blocks are one of the most commonly performed regional anesthetics in children and are performed daily for a host of infra-umbilical surgical procedures. A caudal block is an epidural injection, most commonly of local anesthetic into the epidural space as accessed via the sacral hiatus. In children, the sacral hiatus is a normally occurring aperture in which the epidural space may be accessed with extremely minimal risk; as neural tissue ends more proximally. Due to this measure of safety, caudal blocks are preferred in children when compared with standard lumbar epidurals. Caudal blocks are performed blindly using palpation and tactile feedback to assess if the medication is being administered in the correct location. As a result of blind injection, administration of local anesthetic totally or partially outside of the correct site can often be unnoticed or identified after a significant volume has already been injected. With the potential for toxicity of local anesthetic, this may result in either the inability to give a complete dose or an unintentional and often unnoticed sham block ¿incorrect site of injection¿.

Use of ultrasound has been proposed for identification of caudal block placement and correct medication spread. However, a recent review of the Pediatric Regional Anesthesia Network database reveals that ultrasound is reportedly only used in less that 3% of blocks. The benefit of ultrasound is safe and real-time confirmation of injection. Ultrasound allows the provider to determine with minimal local anesthetic or even saline injection if the correct space is accessed. Without ultrasound, failed blocks are either identified after significant percentage of the total dose of local anesthetic is incorrectly administered or intra or post operatively when the patient demonstrates a significant opioid requirement. This is problematic given that one of the primary benefits of a caudal block in children is the ability to avoid opioids.

Review of local practice here at Texas Children¿s Hospital for quality improvement purposes revealed a failure rate of caudal blocks to be 18%. Failure was defined as a heart rate increase with incision of >20% despite a caudal block and >1MAC of gas for the patient age. These patients all required opioids both intra and post operatively in addition to surgical levels of inhaled anesthetic agent.

Section D: Purpose and Objectives

1) Identify the rate at which blindly placed caudal blocks are not within the epidural space 2) Identify the rate at which ultrasound can guide a wrong block into the correct location 3) Identify if lack of heart rate change on incision can predict successful placement when medication administration is successfully confirmed with ultrasound 4) Identify if after using ultrasound to visualize placement, if concentrations of inhaled agents may be reduced in children

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Child (3-12 yrs), Infant/Toddler (0-36 mos)

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?

Consent will only be obtained from parents/legal guardians. Confidentiality will be maintained by the PI as no patient or provider specific identifiers will be recored aside from consent parental signature. To avoid undue coercion, consenting parents/guardians will be informed that there willingness to participate will not affect their child's treatment course or ability to get a caudal block or have any impact on their care course.

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:

c) Pilot

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.

Single blinded prospective trial in which all patients serve as their own clinical control group.

Inclusion Criteria:

Children ages 0-84 months Infra-umbilical procedure for which a caudal block is already planned American Society of Anesthesiology classifications of 1,2 or 3

Exclusion Criteria:

Associated procedures for which caudal does not provide complete analgesia Incarcerated hernias Emergency procedures Local Anesthetic allergy Sacral dimple Rash over sacrum precluding block Parents/legal guardians unable to consent for surgical procedure in English language Foster Care/Child protective services as guardians Parental Refusal for caudal block or study participation American Society of Anesthesiology classifications other than 1,2 or 3

F2. Procedure

Patients meeting inclusion criteria and following informed consent will be brought back to the operating room. General anesthesia will be induced in the standard manner either by inhalation induction or intravenous induction at the discretion of the anesthesia attending of record. The airway will be secured using an

age/weight appropriately sized device, at the discretion of the anesthesia attending of record. The caudal block will ensue in the same manner regardless of the study at the discretion of the anesthesia attending of record. The attending anesthesiologist will perform or instruct the placement of a caudal block according to their standard of practice. At the time of administration of local anesthetic into the caudal space, the study collaborator (SC) will ultrasound the caudal space keeping the provider placing the block blinded to the imaging. The provider placing the block will inject 0.5mL of preservative free saline. The provider will then be asked to state if they are correctly in the caudal space or not. If the provider feels they are not in the caudal space, they will re-do the procedure. If the provider fails to identify incorrect location and this is noted by ultrasound, the SC will inform the provider to re-do the procedure. After a successful injection (as confirmed by ultrasound) is performed, the patient will be prepped for the procedure in standard manner. The inhaled anesthetic will be titrated until the minimal alveolar concentration is between 0.8-1 MAC for age prior to incision. The anesthesia provider will note the heart rate immediately before and after the first surgical stimulation. Data will be recorded de-identified on the sheet (see attached). The study PI will compare MAC hours (exposure to inhaled anesthetic agent) in patients having undergone caudal block with ultrasound confirmation to those in the retrospective group gathered for quality improvement to ascertain if reduction of exposure to inhaled agent was possible.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 150 Worldwide: 150

Please indicate why you chose the sample size proposed:

A previous study using ultrasound in children for caudal block demonstrated an incidence of 7.1% subcutaneous bulging (failed block) when ultrasound was not used. Using our primary outcome of determination of block failure rate when performing blind (without ultrasound) and assuming a difference of 20% increase in success rate would alter practice and thus be clinically significant using a one sample mean, alpha of 0.05 and a power of 80% would require an enrollment of 99 patients, each serving as their own control. Assuming a study dropout rate of 10% (unknown sacral dimple, etc.) and requirement for additional patients to perform secondary statistical analyses, 150 patients will be enrolled. Analysis performed with JMP statistical software.

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?

Data will be presented as means +/-SD, median (range) and number % when appropriate. Continuous variables will be compared with independent sample t-test or Mann-Whitney U testing for normally distributed data. Odds ratios will be noted for the primary outcome with confidence intervals displayed to achieve CI of 95%. Statistics will be aided by JMP software with P values of <0.05 considered significant.

Section H: 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:

There are no potential risk of discomfort to the patients As with all studies, there is a small risk of loss of confidentiality or data breech.

Section I: Potential Benefits

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

Patient: For the individual patient enrolled, there will be no deviation from the standard of practice of either the anesthetic or regional block. As nearly all providers perform this technique blindly, the patient will have the benefit of immediate recognition of incorrect block eliminating the possibility for inadvertent sham block. In addition, reduced block failure will result in less exposure to opioids and inhaled anesthetic agents.

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

The benefit from this study, should it show that ultrasound is superior for recognizing incorrect placement when compared with blind technique is that fewer inadvertent sham blocks may be performed. Additionally, if reduction of block failure by use of ultrasound can be established, reduced exposure to inhaled anesthetics which have potential adverse effects on neurodevelopment may be possible

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

The study benefits the participant that would undergo a caudal block using a blind technique in that immediate recognition of sham block would be possible allowing for correction of placement. The study would reduce the risk for patients undergoing caudal blocks with incorrect placement that provide a risk of the block with no benefit. This allows the patient to either benefit from the block or avoid wrongly placed medication should the block be aborted. As with all studies, there is a small risk of loss of confidentiality or data breech.

Section J: Consent Procedures

J1. Waiver of Consent

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

NA

J1a. Waiver of requirement for written documentation of Consent

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

NA

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.

The PI or approved collaborators as listed in this protocol will recruit patients that will be undergoing procedures for which a caudal block will already be provided as standard of care. Consent for the anesthetic including the caudal block will be taken by the attending anesthesiologist of record or designated associate (resident/fellow). If inclusion/exclusion criteria are met, the PI or approved collaborators will approach the consenting parent for consent. The parent will be informed that no changes to their child's care will be made by participation in this study. They will be informed that study participation is not required and that failure to participate will not, in any way alter the care provided to their child. They will also be informed that consent for participation can be withdrawn at any time.

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?

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?

NA

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

NA

Specific information concerning alcohol abuse:

NA

Specific information concerning drug abuse:

NA

Specific information concerning sickle cell anemia:

NA

Specific information concerning HIV:

NA

Specific information concerning psychiatry notes:

NA

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

NA

Full Social Security #:

NA

Partial Social Security # (Last four digits):
NA

Billing or financial records:
NA

Photographs, videotapes, and/or audiotapes of you:
NA

Other:
NA

At what institution will the physical research data be kept?
NA

How will such physical research data be secured?
NA

At what institution will the electronic research data be kept?
NA

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
NA

Such electronic research data will be secured via Other:
NA

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

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

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.
The PI will de-identify all data using a random number generator to create a study number. Only the PI will have access to the patients medical record number which will not be shared between collaborators. this will be stored on a separate paper in a secured locked drawer in the secured anesthesia office at TCH

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.
Standard of care will be applied No additional charges are to be acquired by the patients from 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:

N/A

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?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

Section P: Device Studies

Does this study need an IDE?

No

Regarding your device study, could potential harm to subjects be life-threatening?

No

Regarding your device study, could potential harm to subjects result in permanent impairment of a body function?

No

Regarding your device study, could potential harm to subjects result in permanent damage to a body structure?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

None