Columbia University Medical Center Consent Form

Attached to Protocol: IRB-AAAQ0916
Principal Investigator: Richard Smiley (rms7)
IRB Protocol Title: Chloroprocaine versus bupivacaine spinal anesthesia for cervical cerclage

Consent Number: CF-AAAT6471
Participation Duration: 12 hours
Anticipated Number of Subjects: 60

Contact

Contact	Title	Contact Type	Numbers
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Research Purpose
You are invited to participate in a research study which is designed to determine whether or not spinal anesthesia with the local anesthetic drug, chloroprocaine, wears off faster than the local anesthetic drug, bupivacaine, and results in faster discharge from the post-anesthesia care unit after surgery.

Background:

You are scheduled to undergo cervical cerclage with spinal anesthesia. Over 90% of these procedures at CUMC are performed with spinal anesthesia because this allows the woman to be awake, to breathe on her own, and limits the amount of medication that crosses to the fetus. Because the procedure usually lasts approximately 30 minutes, an anesthetic technique with a relatively short duration of action and recovery is indicated. Bupivacaine is now the most common local anesthetic used for this procedure. Bupivacaine is safe and has been preferred over other medications such as lidocaine, because it is associated with a low incidence of a complication from spinal anesthesia known as “transient neurologic symptoms” – a condition where pain and cramping in the b uttocks and lower extremities can be experienced for several days. Bupivacaine is a long-acting local anesthetic agent and therefore has the disadvantage of a prolonged anesthetic recovery that may last a few hours.

Chloroprocaine is a local anesthetic with a fast onset and short duration that may be used for spinal anesthesia for ambulatory procedures. Chloroprocaine is currently used at CUMC for spinal anesthesia for ambulatory surgical patients, especially for lower extremity orthopedic procedures such as knee arthroscopy. It is also used at CUMC for pregnant patients like yourself.

In our study, patients undergoing cervical cerclage under spinal anesthesia will be randomized, by a process similar to flipping a coin, to receive either chloroprocaine or bupivacaine for their spinal anesthesia. We will observe and compare how fast the anesthesia sets in, how comfortable you are during your surgery, how long it takes to wear off and how long it takes to be discharged from the Post-Anesthesia Care Unit. We will call you the next day to check if you are having any complaints or concerns related to the spinal anesthesia you received.

Information on Research

We are doing this research study to compare the onset, action and duration of the local anesthetic medications chlorprocaine and bupivacaine for spinal anesthesia. You are being asked to take part in this study because you are undergoing cervical cerclage with spinal anesthesia. About 50 people are expected to be enrolled in this study at CUMC. Off label use of an approved drug chloroprocaine is being used in an investigational manner (not for the purpose that it is approved for) in this research study. This means that chloroprocaine has been approved by the Food and Drug Administration (FDA) for use in nerve blocks, but it has not been approved for epidural or spinal anesthesia. You should understand that although chlororprocaine is not approved by the FDA for use in this manner, at CUMC and many hospitals around the US, we have a lot of experience using chloroprocaine quite safely for both epidural and spinal anesthesia. In fact the use of chloroprocaine at CUMC between 2010 and 2013 was studied by members of our Department and it was reported that out of 358 cases in which chloroprocaine was used for spinal anesthesia, there were no complications noted. Because of the safety, low toxicity and fast onset of chloroprocaine, it is also the drug we use most commonly for epidural anesthesia for emergency surgeries in pregnant women at CUMC.

Risks

Spinal anesthesia with either relatively low dose bupivacaine or choroprocaine is considered to be safe and does not present significant additional risk to receiving routine spinal anesthesia care at CUMC. Both medications are currently used at CUMC for anesthesia for cerclage. To the best of our knowledge, taking part in this study will not hurt you.

Benefits

You may or may not receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this study is that patients in the chloroprocaine group may have earlier resolution of the anesthesia block and have earlier discharge from the post-anesthesia care unit.

Alternative Procedures

You may choose not to take part in this research study.

Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur,

although it is highly unlikely. The research file that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. The following individuals and/or agencies will be able to look at and copy your research records: - The investigator, study staff and other medical professionals who may be evaluating the study - Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB') - The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP') and external, exclusive contractors who may be reviewing compliance with research policies.

Research Related Injuries

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room. If you are injured or harmed as a result of participating in the study and receive medical care through the NewYork-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. Columbia University and NewYork-Presbyterian Hospital (NYPH) are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Compensation

You will not receive any payment or other compensation for taking part in this study.

Additional Costs

Taking part in this study will not involve additional costs to you. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

Voluntary Participation

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and New York Presbyterian Hospital.

Additional Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

Signature

Study Subject
Print Name_____Signature_____Date_____

Person Obtaining Consent
Print Name_____Signature_____Date_____

Subject Name
Print Name_____