

Scott & White Hospital & Clinics

Clinical Research at Scott & White

Study Title: Spinal 2-Chloroprocaine: A Comparison with Bupivacaine for Post-Partum Tubal Ligations

Project ID#: 8761

Department: Anesthesiology

Sponsor: Scott & White Hospital

Brief Synopsis of the Study

Condition(s):	Treatment(s):
Elective post-partum tubal ligation.	Spinal 2-Chloroprocaine or bupivacaine anesthetics

The purpose of this research study is to evaluate the effectiveness of nesacaine MPF vs bupivacaine when used for spinal anesthetic (numbing agent) in patients scheduled for elective post-partum bilateral tubal ligations. Additionally, this research study will evaluate the incidence (how often they occur) of spinal headaches and length of time until return of sensory (return of full feeling and movement) after the spinal anesthesia. Bupivacaine is the standard medication used for spinal anesthetic at this time. Nesacaine MPF is a U.S. Food and Drug Administration (FDA) approved medication but it is not specifically indicated for use in spinal anesthesia. Its use for spinal anesthesia is considered “off-label” or investigational.

Who is eligible to participate in the study?

Age: 18 years of age or older

Gender: F

To participate in this research project, you must be at least 18 years of age and scheduled to undergo an elective post-partum bilateral tubal ligation.

You should not participate in this study if any of the following apply to you:

- You have an allergy or intolerance to local anesthetic medications
- You are not a candidate for spinal anesthetic
- You have an allergy to latex.

What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)

You will be randomly assigned (like the flip of a coin) to one of 2 groups. Group A will receive 15 mg of bupivacaine. Group B will receive 60 mg of nesacaine. Neither you nor the physicians and staff associated with this study will know which group you were assigned to. However, if it becomes medically necessary, your physician can find out from the pharmacy what you were given. All study medications will be given to you as a one time, spinal injection (into your back). After you receive the study spinal anesthetic agent, you will be evaluated every 5 minutes for sensory blockade (numbness) for the first 30 minutes, then at 10 minute intervals until complete resolution of numbness (full feelings have returned). You will be asked questions about your ability to move your legs and feet at 10 minutes after injection, at the conclusion of surgery and every 10 minutes until full movement ability has returned. The day following surgery, you will be asked questions about the presence of headache, backache or other symptoms. This will end your study participation.

For More Information Contact:

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