

Scott & White Hospital & Clinics

Clinical Research at Scott & White

Title: An Investigation of Respiratory Depression and Airway Obstruction in Post-Operative Laparoscopic Gastric Bypass Patients Receiving Either Dexmedetomidine or Placebo

Project ID#: 050276

Department: Anesthesia

Sponsor: Hospira, Inc.

Brief Synopsis of the Study

Condition(s):	Treatment(s):
Patients who are scheduled to have laparoscopic gastric bypass surgery	Infusion of study drug (dexmedetomidine) or placebo (normal saline) during surgery and six hours during recovery.

Why is the study being done?

Dexmedetomidine is a new medicine that reduces the need for opioid pain medications. Opioid pain medications are routinely used to reduce pain after major surgery. Pain reduction is important because it reduces stress to the body after surgery and improves the patient's ability to breathe deeply.

Rarely, they can cause impaired breathing by causing airway obstruction, sedation, or a decrease in the brain's incentive or drive to breathe. These are well known side effects. For this reason obese patients and patients with obstructive sleep apnea often receive less pain medicine.

Another way to reduce the risk of breathing problems in obese patients or patients with obstructive sleep apnea (a condition in which a patient has difficulty breathing while asleep) is to give medicines that reduce the pain by a different mechanism so that not as much opioid pain reliever is needed. One such medicine is dexmedetomidine.

The purpose of this research study is to see whether dexmedetomidine can reduce the need for opioid pain medications, and the amount of respiratory depression, and airway obstruction that they cause, in patients who are scheduled to have laparoscopic gastric bypass surgery.

Who is eligible to participate in the study?

Age: Greater than 18 years of age

Gender: M/F

Patients who are scheduled to have laparoscopic gastric bypass surgery greater than 18 years of age.

Excluding:

- Pregnancy
- Diagnoses with hepatic insufficiency (liver not working properly)
- Allergy to Codeine, Morphine or Dexmedetomidine.
- History of advanced heart block
- Severe heart dysfunction, heart failure or have a ventricular ejection fraction less than 45% (a test that measures the blood in the heart's ventricle at rest and during the contraction of the heart).
- On the day of surgery, your blood pressure is greater than 105 diastolic or systolic greater than 190

What is involved if I participate?

- **Preoperative visit:**
 - A. Informed consent completed
 - B. Demographic and medical history will be obtained
 - C. Laboratory tests obtained
 - D. You will be asked to complete the Berlin Questionnaire.
 - E. You will be asked to have a Embletta Sleep Apnea monitor test done (a machine to measure breathing problems).
- **Day Surgery:**

Vital signs will be obtained
- **Operating Room:**
 - A. Standard monitors will be applied
 - B. Infusion of study drug (dexmedetomidine) or placebo (normal saline) will be started
 - C. Vital signs will be recorded
- **Recovery Room:**
 - A. Infusion of either the study drug or the placebo will continue for the following 6 hours in the recovery room area.
 - B. You will remain within the recovery room area during this time
 - C. You will be asked to rate your pain
 - D. You will have a PCA machine set up, to help you with pain you may be having by administering pain medication
 - E. You will be connected to an Embletta Sleep Apnea monitor (a machine to measure breathing problems).

- **After 6 hours of receiving either study drug or placebo, while you are in the recovery room:**
The study drug or placebo infusion will be stopped, and you will begin routine care.
- **Follow up contact:**
You will be contacted from a member of the study staff, to ask you to rate your overall pain control satisfaction score during your hospital stay.

Duration:

This study begins at preoperative time until 6 hours after you arrive in the recovery room, unless you decide to stop your participation. Information about your pain, need for pain reliever, any complications, length of hospital stay, will be documented during this time and for the following 24 hour period.

Who Can I Contact For Additional Information On This Trial?

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