Principal Investigator: Dr. Pavithra Ranganathan,
Department: Anesthesiology
Protocol Number: 1306055796
Study Title: **Does Single Intraoperative Bolus Dexmedetomidine Significantly Reduce Narcotic Requirements during Postoperative Period in Bariatric Patients?**

Study Personnel: Dr. Attaallah Ahmed, Dr. Mathew Ellison, Dr. Daniel Sizemore
Co-Investigator(s): Dr. Lawrence Tabone and Dr. Mathew Gurkha.

Contact Persons

Dr. Lawrence Tabone or Dr. Pavithra Ranganathan at Ext# 79484 or pager number 2455
In the event you experience any side effects or injury related to this research, you should contact Dr. Ranganathan at (304) 598-4000 pager number 2455. (After hours contact: Anesthesia Charge at (304) 598-4000 ext 76263). If you have any questions, concerns, or complaints about this research, you can contact Dr. Lawrence Tabone's office: 304-598-4000 ext: 74890 or pager 0081 or Dr. Pavithra Ranganathan at 304-598-4000 ext. 79484 or pager 2455.
For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.
In addition if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact the Office of Research Integrity and Compliance at 304-293-7073.

Introduction

You,_____, have been asked to participate in this research study, which has been Explained to you by .....This study is being Conducted by Dr. Lawrence Tabone and Dr. Pavithra Ranganathan in the Department of Anesthesiology at West Virginia University sponsored by Department of Anesthesiology at West Virginia University.

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Purpose(s) of the Study

The purpose of the study is to determine if giving a medication called dexmedetomidine, which is a commonly used sedative, during weight loss surgery will reduce the amount of pain medications needed after surgery.

There will be two groups in the study. Both groups will receive a standard general anesthetic administered by me or one of the other investigators in the study. You may either receive the medication- Dexmedetomidine or saline, through your IV as part of your study. During the recovery period you will be given a pain pump – which is a button to press if you have any pain. The pain pump will give you pain medication on demand. Your vital signs, your medications and all related information entered into your electronic medical record will be used for the study purposes only.

Description of Procedures

You will be placed in one of two groups, a control group or a study group. If you are in the control group (as assigned by the pharmacist) you will receive your routine general anesthetic and IV saline. If you are in the study group- you will receive your routine general anesthetic and the medication – dexmedetomidine.

Neither the anesthesia provider nor the recovery room nurse knows which part of the study group you belong to. You will be randomly selected to which group you belong to; like flipping a coin. That information will be kept confidential and coded so that there will be no link to any information that identifies you. In case of any medical problems after anesthesia and surgery; we will access that information in order to provide appropriate medical care.

When you awaken from surgery you will be taken to post anesthetic recovery unit commonly called the PACU. You will be given a pain pump with a button to press when you need pain medications. It will deliver your pain medication on demand by you. The amount of pain medication delivered to you will be routinely recorded by the PACU nurse into the electronic medical record. You will be kept in PACU for approximately 4 hours. You will be reevaluated by me or my co-investigator before you leave the PACU to go to your room. You will not be asked to do anything beyond what would be considered standard during the recovery period. You will be monitored at all times by attending anesthesiologist, anesthesia resident or nurse anesthetist and or PACU staff. All emergency equipment and medications will be immediately available to assure your safety. Rescue doses of pain medication will be readily available should you experience pain above and beyond what can be given to you by your pain pump to ensure your comfort after surgery. Your safety and comfort is our priority and we will not do anything that may jeopardize that.

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886 Chestnut Ridge Road
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Subject's Initials_____
Date_____

Risks and Discomforts
It is anticipated that you will not face any additional discomfort for taking part in the study beyond what is considered normal for the procedure performed. However, dexmedetomidine does have specific side effects from including but not limited to an allergy to the medication, slow heart rate change in your blood pressure and sleepiness.

Alternatives
You do not have to participate in this study.

Benefits
Potential benefits to you may be a decrease in pain after surgery in the first 4 hours and a decrease in the side effects of the pain medications like nausea, constipation, breathing problems, decreased stress response during surgery and decreased anxiety after surgery.

Financial Considerations
You will not incur any expense or costs in relation to this study.

HIPAA
We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Confidentiality
Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities (including the FDA if applicable) without your additional consent. In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you. In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

Persons/Organizations Providing the Information
West Virginia University Hospitals

Persons/Organizations Receiving the Information

• The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals. It also includes each site's research staff and medical staff
• Health care providers who provide services to you as part of this research study.
• The members and staff of any Institutional Review Board (IRB) that oversees this research study.
• West Virginia University Office of Research Compliance and Office of Sponsored Programs.
• West Virginia University Clinical Trials Research Unit.

The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as, nursing and staff notes, demographic data, anesthesia record, post anesthesia care data and medication given to you on the day of surgery.

The Information is Being Disclosed for the Following Reasons

• Review of your data for quality assurance purposes
• Publication of study results (without identifying you)
• Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; conducting performance reviews of the study drug; evaluating other products or therapies for patients; developing a better understanding of disease; improving the design of future clinical trials

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Dr. Pavithra Ranganathan at ext. # 79484 or pager number 2455 email: ranganathanp@wvuhealthcare.com.
Phone: 304-598-4122 One Medical Center Drive, P.O. Box 8255, Morgantown, WV 26506.
If you cancel this authorization, any information that was collected already for this study cannot be withdrawn.
Once information is disclosed, according to this authorization, the recipient may redisclose it and then the information may no longer be protected by federal regulations. You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.
This authorization will expire at the end of the study unless you cancel it before that time.

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Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. Refusal to participate or withdrawal will not affect your care and will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care. In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation. You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

Signatures

Signature of Subject

_____

Printed Name

Date Time

_____

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Investigator or Co-Investigator

_____

Printed Name Date Time

_____

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