CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Preoperative Acetazolamide for Improved Pain Control Following Laparoscopic Hysterectomy

Study to be Conducted at: *Greenville Memorial Hospital*
700 Grove Road
Greenville, SC 29605

Sponsor Name: *Prisma Health, Department of Obstetrics and Gynecology*

Principal Investigator: *Paul B. Miller, MD* *Phone: (864) 455-5890*

KEY INFORMATION

You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study doctor to explain anything you do not understand.

This study looks at whether giving patients a medicine called acetazolamide (also called Diamox) before they have laparoscopic hysterectomy may decrease postoperative (after surgery) pain. A laparoscopic hysterectomy is the removal of the uterus and or cervix through small incisions in your abdomen. During laparoscopic surgery, carbon dioxide gas is used to inflate the abdominal cavity, creating a space for the surgeon to clearly see inside your abdomen by lifting the abdominal wall for a better view. The gas may cause an irritation that leads to abdominal, pelvic, or right shoulder pain during the first 24 hours after surgery. Acetazolamide, given before surgery, may stop the process that could cause irritation, therefore, it may reduce postoperative pain.

The Institutional Review Board of Prisma Health has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations.

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.

PURPOSE

You are being asked to participate in this study because you are scheduled for laparoscopic hysterectomy. The purpose of the study is to see if acetazolamide reduces postoperative pain when given before surgery.

If you participate, you will have a two out of three chance of receiving a capsule of acetazolamide in the pre-operative area within an hour before your operation, or you may receive a placebo (non-active) capsule (one out of three chances). The surgical procedure that follows as well as all the other medications given to you by the anesthesia and recovery room teams will be the same as everyone else having laparoscopic hysterectomies. In the recovery room, you will be asked to answer a pain score questionnaire from zero to ten where zero is no pain and ten is excruciating pain. This will be repeated at two, four, and 24 hours after surgery. The last score will be given over the phone to a research coordinator.

Acetazolamide is a drug that is already approved by the Food and Drug Administration (FDA) for the treatment of glaucoma (increased pressure within the eyeball), altitude sickness, swelling, and seizures. If you get the drug, you will receive one dose. About 100 study participants will be enrolled.

This research study is being done to see if acetazolamide can reduce the use of postoperative pain medicine. Your participation will last until 24 hours after your surgery.

HOW THE STUDY WORKS

- Your surgeon identifies you as an eligible laparoscopic hysterectomy patient.
- You will receive information about the study and have an opportunity to ask questions about it at your preoperative appointment.
- If you agree to participate, you will sign this informed consent form.
- You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like drawing straws. Neither you nor your doctor will choose what group you will be in. You will have a 2 out of 3 chance of receiving the study drug.
- In the preoperative area, you will be asked by a research study team member to give a baseline pelvic pain score and a right shoulder pain score where 0 is no pain and 10 is excruciating pain.
- You will then receive a capsule of the study drug (acetazolamide) or a placebo capsule in the preoperative area within one hour of planned start of surgery.
- You will have your surgery as planned. Neither you, your surgery team, your anesthesia team, nor your recovery team will know what study group you are in.
- When you wake up in the recovery room a study team member will ask you the pain score questionnaire.
- Pain scores will be repeated at two and four hours after surgery.
- You will be given a copy of a pain scale to take home with you.
- 24 hours after surgery you will be called by a research study team member to check on your current pain scores and the amount of pain medicine you took at home after surgery.

- Your electronic medical record will also be reviewed by a research coordinator to record the reason for surgery, how long it lasted, whether any complications occurred, whether you received a blood transfusion, what medicines you received during and after surgery, and how long you stayed in the hospital.

POSSIBLE RISKS

Any treatment has possible side effects. The treatments and procedures used in this study may cause all, some, or none of the side effects listed. There is always the risk of very uncommon or previously unknown side effects.

POSSIBLE SIDE EFFECTS

Serious

- Metabolic acidosis (buildup of acid in your blood)
- Electrolyte imbalance (levels of minerals in your body are too high or too low)
- Skin rashes
- Liver impairment
- Anemia
- Suppression of bone marrow (decrease in bone marrow activity resulting in reduced production of blood cells)
- Low platelets
- Low white blood cells
- Seizures
- Paralysis
- Kidney stones

Common

- Fatigue
- Taste changes
- Loss of appetite
- Nausea
- Vomiting
- Nerve tingling
- Diarrhea
- Frequent urination
- Ringing in the ears
- Hearing changes
- Blurred vision
- Drowsiness
- Confusion
- Rash
- Sensitivity to light

- Blood or sugar in the urine
- Blood in bowel movements

These complications can sometimes lead to serious illness requiring hospitalization or lead to death.

Most studies reporting side effects looked at people who took multiple doses of the drug for multiple days. If you get the drug, you will receive one dose.

As with all medications, side effects may include allergic reactions. Allergic reactions may range from minor itching or rash to major reactions, which can lead to death.

It is possible that receiving the study drug with your regular medications, supplements, or some food (for example, grapefruit juice) may change how the study drug, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study. Tell the study doctor if you are taking any drugs, or non-prescription medications or supplements, including vitamins or herbs, other than those being used in this research study because of the risk of possible and/or serious drug interactions. Tell anyone who gives you medical care that you are participating in a research study.

POSSIBLE BENEFITS

It is not possible to know whether or not you may benefit from participating in this study. The treatment or procedures you receive may even be harmful. The information gained from this study may be useful and may help others.

ALTERNATIVE (OTHER) TREATMENTS

You can still receive evaluation and treatment for your condition if you do not participate in this study. Discuss any alternative treatments with your regular doctor and/or the study doctor before you decide to participate. The decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

- You may choose to have the standard of care treatment, which are the normal types of pain medicine given before, during, and after surgery.

Please discuss these choices with your doctor.

NEW INFORMATION

Your doctor will tell you about new information that may affect your willingness to participate in this research study. Alternatives, or other choices, concerning your care will be discussed at that time.

There are no plans to share individual research results with you.

COST TO YOU FOR PARTICIPATING IN THIS STUDY

Study funds will pay for all study-related items (the acetazolamide capsule or placebo capsule) and services required by the research. We will bill you or your health insurer for items and services that are not part of the research and are part of your routine care. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will be responsible for the cost of any care not covered by insurance or study funds.

If you have any questions or are unsure about the costs from taking part in the research, please speak with the study doctor or staff.

PAYMENT FOR PARTICIPATION

You will not be paid for participating in this study.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION

We will provide you the care needed to treat any injury, or illness, that directly results from taking part in this research study. We reserve the right to bill your insurance company, the sponsor or other third parties for the care you get for the injury. You may be billed for these costs. For example, if the care is billed to your insurer, you will be responsible for the payment of any deductibles and co-payments required by your insurer.

The study sponsor, Prisma Health, or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

However, if you decide to stop study participation, you are encouraged to talk with your doctor regarding safe removal from the study. Further treatment would be discussed at that time.

If your participation in this research study is stopped, your study doctor will discuss any tests or procedures that might be needed for your health and safety, but you may refuse any or all of these tests or procedures. Following this discussion with your study doctor, you still have the right to refuse any or all of these tests or procedures.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, the study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical

records that is related to the research study. The study doctor and his/her research team will use and disclose (release) your health information to conduct this study. This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Some of the organizations/entities that may receive your information are:

- The Institutional Review Board, which is a group of people who review research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration (FDA) and the groups it works with to review research.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study. Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to the study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

If you have any questions about the privacy of your health information, please ask the study doctor.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Prisma Health Office of Human Research Protection for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. Please contact the Office of Human Research Protection using the telephone number 864-455-8997.

Principal Investigator Name: Paul B. Miller, MD
Telephone Number: 864-455-1600

CONSENT TO PARTICIPATE

The study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given the opportunity to review my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____

Printed Name of Participant

_____ _____ _____

Signature of Participant Date Time

_____

Printed Name of Person Obtaining Consent

_____ _____ _____

Signature of Person Obtaining Consent Date Time

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