# The POUR Study: Effects of Neuromuscular Reversal Agents on Postoperative Urinary Retention (POUR) Following Laparoscopic Inguinal Hernia Repair

NCT05276804

IRB Approved Date: 11.20.2023

**ATRIUM HEALTH**
**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**
**AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

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| **Sponsor / Study Title:** | **Merck Investigator Studies Program (MISP) / The POUR Study: Effects of Neuromuscular Reversal Agents on Postoperative Urinary Retention (POUR) Following Laparoscopic Inguinal Hernia Repair** |
| **Principal Investigator: (Study Doctor)** | **B. Todd Heniford, MD** |
| **Telephone:** | [redacted] |
| **Address:** | [redacted] |

## INTRODUCTION

Dr. Todd Heniford is asking you to participate in this study that aims to improve rate of urinary retention following laparoscopic inguinal hernia repair. You are being asked to take part because you have been diagnosed with an inguinal hernia and are undergoing surgical repair. The purpose of this study is to assess the effect of the Sugammadex, on postoperative urinary retention. During surgery, a medicine is given to paralyze muscles. As surgery is ending, Sugammadex can be given to reverse muscle paralysis. Relaxed muscles, if not reversed, may contribute to urinary retention. The rate of urinary retention is normally 7-8% following inguinal hernia repair. Thus far, Sugammadex has been found to reduce the rate of postoperative urinary retention. Patients enrolled in this study will be compared to previous patients who underwent reversal with the reversal agent neostigmine.

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

## HOW THE STUDY WORKS

If you agree to be in the study, you will undergo laparoscopic inguinal hernia repair with one of the surgeons in the Division of Gastrointestinal & Minimally Invasive Surgery. The operation will be performed in standard fashion. Following surgery, you may or may not receive Sugammadex to reverse the paralytic received prior to surgery. This is dependent upon eligibility criteria and/or any issues during surgery that may exclude you from participation. Sugammadex is FDA approved as a reversal agent and is considered standard of care following laparoscopic inguinal hernia repair, however, is not used as standard of care at this facility. You will be monitored in the postoperative recovery room. Postoperative urinary retention will be defined as

the need for catheterization due to lack of urination within six hours after surgery. Other operative details (i.e. age, gender, ASA class, length of stay, prior surgeries, etc.) will be recorded as well as the cost of the operation and any need for subsequent hospitalization.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

One-hundred and forty (140) participants will be enrolled into the prospective group of this study. These 140 participants will receive Sugammadex as part of this study. One-hundred and forty (140) participants will be included in the retrospective group of this study as a comparison group. These 140 participants have had a previous inguinal hernia repair at our institution but did not receive Sugammadex. The total number of patients in this study will be 280.

## WHAT IS INVOLVED IN THE STUDY?

This study will consist of the following steps:
Step 1: You will be seen in clinic for a consultation visit
Step 2: The attending surgeon will introduce the study to you
Step 3: A member of the research team (attending surgeon, fellow, resident, research manager or research associate) will explain the study to you and, if interested, will consent you to participate in the study
Step 4: The attending surgeon will perform your procedure using Sugammadex
Step 5: Post operative urinary retention will be assessed at 6-hours after surgery. This will be assessed by the ability to void the bladder (urinate)
Step 5: You will be seen back in clinic 1-2 weeks post-surgery for a standard of care follow up visit. At this visit you will be asked to complete a quality of life questionnaire (Carolinas Comfort Scale). This questionnaire will allow the research team to compare your quality of life after receiving Sugammadex to the quality of life of the patients in the retrospective group who did not receive Sugammadex

## INCLUSION/EXCLUSION CRITERIA:

*Inclusion Criteria*:

- 18 years of age and older
- Undergoing laparoscopic inguinal hernia repair at Carolinas Medical Center by attending surgeons within the Division of Gastrointestinal and Minimally Invasive Surgery
- Unilateral or bilateral inguinal hernia repair; may have concurrent umbilical hernia repair performed
- Agreeable to participation in the study

*Exclusion Criteria*:

- Patients who are having concurrent ventral or flank hernias repaired at time of operation or are having an inguinal hernia repair along with another operation (e.g. laparoscopic cholecystectomy)
- End-stage renal disease (Creatinine clearance less than 30)
- Neuromuscular disease
- Prior adverse reactions to Sugammadex
- Patients who do not provide consent for the study

## RISKS

We overall anticipate minimal risks in participation of this study. Common side effects of Sugammadex are dizziness, tremor, lightheadedness, hypotension and tachycardia, but they are rare. Patients with kidney disease and neuromuscular disease are not allowed to participate due to potentially worsening of those pre-existing conditions. Other risks include loss of confidentiality, which will be low as patient information is de-identified and the data is password protected.

### Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

## BENEFITS

The possible benefit is that you will not have postoperative urinary retention following laparoscopic inguinal hernia repair. This will avoid need for catheterization and potentially hospitalization.

## ALTERNATIVE PROCEDURE/TREATMENT

If you choose not to participate in this study, your hernia will continued to be treated with standard of care procedures. Throughout the study, your participation will be completely voluntary.

## ADDITIONAL COST

You will not have any additional costs as a result of participation in this program. Merck will cover the cost of the Sugammadex.

## COMPENSATION

There will be no monetary compensation for participating in this study.

## COMPENSATION FOR INJURY

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing this consent form.

## WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, which will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change

your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

## NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

## CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

## AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

**If you wish to participate in this research study, you**

_____

**Printed Name of Research Subject**

**must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:**

If you wish to participate in this research study, you must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

**The POUR Study: Effects of Neuromuscular Reversal Agents on Postoperative Urinary Retention (POUR) Following Laparoscopic Inguinal Hernia Repair**

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Atrium Health Employees
- Atrium Health Institutional Review Board

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by the you in writing as described above.

_____
Signature of participant or participant's Legally Authorized Representative

_____
Printed name of participant or participant's Legally Authorized Representative

_____
Date

**FINANCIAL INTEREST OF INVESTIGATOR**
The doctors will receive no financial benefit in any form by asking you to participate in this study.

**QUESTIONS**
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, please contact the study doctor listed on page one of this form.

## STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____/____/____ _____
Signature of Research SubjectDate/Time

_____
Printed Name of Research Subject

## STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____/____/____ _____
Signature of Person Explaining ConsentDate/Time

_____
Printed Name of Person Explaining Consent