Prophylactic Antibiotic Administration for Bladder OnabotulinumtoxinA Injection

NCT05719285

09/13/2022

The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Single-Dose versus Multi-Dose Prophylactic Antibiotic Administration for Bladder OnabotulinumtoxinA Injection
Sponsor: None
Principal Investigator: Emily Slopnick, MD 440-695-4000
Study Coordinator: Lauren Gleich, DO, 216-314-3997
After hours phone contact #: Lauren Gleich, DO 216-314-3997

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are currently receiving bladder onabotulinumtoxinA (Botox). The purpose of this study is to assess the rates of urinary tract infection (UTI) after bladder onabotulinumtoxinA (Botox) with different durations of antibiotics after injection.

You will be asked to report any symptoms of a UTI or inability to urinate in the 4 weeks following your bladder onabotulinumtoxinA (Botox) injection. If you have symptoms of a UTI during this time, you will be asked to give a urine sample at the lab. We will give you urine collection materials (measuring cup and collection tube) and instructions and we will ask you to go to one of the bathrooms in our building to collect the urine. Once the urine sample is collected, you will be started on antibiotics.

Your participation in the research will last about 4 weeks.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

You may not want to participate in this study if you do not want to take more than one dose of antibiotics following your bladder Botox injection or if you are unable to provide a urine sample if you develop symptoms of a UTI.

More detailed information about the risks of this study can be found in the section labeled

"Risks."

Why might you choose to volunteer for this study?

You may benefit from this study by potentially decreasing your risk of developing a UTI following your bladder onabotulinumtoxinA (Botox) procedure. You may not receive direct benefit from being in the study, however, taking part may help patients receiving bladder onabotulinumtoxinA (Botox) receive better care in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?

The alternative to being in this study is to not take part. In this case, you will still undergo your regularly scheduled procedure.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

Do the researchers or institution have any conflicts of interest relating to this study?

No. If you have any questions regarding conflicts of interest, please ask you study doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

This study is being done to help establish the best regimen for preventative antibiotics in patients undergoing bladder onabotulinumtoxinA (Botox) therapy. Currently, there is no specific guidance on what antibiotic type, duration, or route is best for bladder onabotulinumtoxinA (Botox).

How Many People Will Take Part in this Study?

Approximately 100 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

The way your bladder onabotulinumtoxinA (Botox) is administered will not change from previous injections. The specifics of the procedure (dose, number of injections, etc.) will be determined by your urologist.

You will receive either one or six doses (3 days) of antibiotics with standard bladder onabotulinumtoxinA (Botox). You will be randomly selected to be in one of two groups:

- Group 1: will receive one dose of oral antibiotic prior to bladder onabotulinumtoxinA (Botox) injection.
- Group 2: will receive one dose of antibiotic prior to bladder onabotulinumtoxinA (Botox) injection and additional antibiotics for a total of three days (6 doses) of antibiotic administration.

The antibiotic for Group 1 and the first dose of antibiotic for Group 2 will be given to you during your office visit. If you are in Group 2, a prescription for 5 more doses of antibiotic will be sent to your pharmacy. You will need to take the antibiotic twice a day (every 12 hours) for 3 days total.

You will be followed for 4 weeks after your bladder onabotulinumtoxinA (Botox) injection. At 4 weeks, Dr. Lauren Gleich or another member of the study staff, will call you to ask about any UTIs, difficulty with urination, or side effects from the antibiotics or onabotulinumtoxinA (Botox). This phone call should take less than 5 minutes if there have been no events to report. If any of the above are reported, the phone call may take longer.

If during these 4 weeks, you experience any symptoms of a UTI, inability to urinate or fully empty your bladder, or adverse effects from the antibiotics or onabotulinumtoxinA (Botox), you should report these to Dr. Lauren Gleich at 216-314-3997.

Symptoms that should be reported include: new or worsening frequency, urgency, burning or pain with urination, blood in the urine, pain in the bladder, pelvis or back, fevers or chills, or inability to urinate or completely empty your bladder.

The following are the current standard of care:

If you have any UTI symptoms, you may be asked to provide a urine specimen at a Cleveland Clinic lab. We will give you urine collection materials (measuring cup and collection tube) and instructions and we will ask you to go to one of the bathrooms in our building to collect the urine. Once the urine sample is collected, you will be started on antibiotics. These antibiotics may be stopped or changed based on the results from the urine culture. Your urine sample will be discarded once the urine culture is complete.

If you have symptoms of urinary retention or incomplete bladder emptying, you may be asked to come in for a nurse visit to check how well your bladder empties. This is done with a bladder scanner. You urinate and a nurse will use the bladder scanner (a small ultrasound machine) to check the amount of urine remaining in your bladder. The amount of urine left in your bladder will be reported to your urologist. If they feel the number is too high, they may recommend placing a catheter or learning to insert a temporary catheter on your own to drain the bladder. This visit should take less than 30 minutes to complete.

How will my data/specimens be used?

Your data may be sent outside of the Cleveland Clinic for presentation of our findings to other health professionals. Any personal information that could identify you will be removed before the data are shared.

Will I be notified of the results of the tests/studies on my samples?

When samples are collected and analyzed, there is the chance of finding something that may be important for your care. You will be informed of any results that are relevant to your clinical care.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

The alternative to participating in this study is to receive the standard of care.

3. RISKS

What are the risks of participating in the research study?

The only risk specifically related to the study is an adverse reaction to additional doses of an antibiotic. Additional risks associated with bladder onabotulinumtoxinA injection include:

- Urinary Tract Infection (11%)
- Urinary Retention (4%)
- Adverse Reaction to the onabotulinumtoxinA (Botox)

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential using the following safeguards:

- Identifying information, such as your name or medical record number, will be removed from your data results.
- We will replace your identifying information with a code that does not directly identify you.
- The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team.
- Data will be stored on a password protected computer accessible only by the research team.
- Any information that can identify you will remain confidential.
- Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Questionnaire/Survey Research

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

4. BENEFITS

What are possible benefits of participating in the research?

Participation in this study may help to prevent a UTI after your procedure. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

5. COSTS

Are there any costs to you if you participate in this study?

There is no cost to you to be in this research study.

Some of the services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your health insurance plan. Examples of these routine services include: urinalysis, urine culture, nursing office visits, antibiotics. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

6. PAYMENT

Are there any payments to you if you participate in this study?

No.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If

you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is

minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Emily Slopnick, 9500 Euclid Ave, Q10, Cleveland, 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Language

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Dr. Lauren Gleich, DO at 216-314-3997. During non-business hours, weekends and holidays, please contact 216-314-3997. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

If you would like to withdraw from the study at any time, please inform your urologist, or another member of the urology care team. There is no risk to withdrawing from the study. If you chose to withdraw, you may be contacted by the Study Coordinator through MyChart or by phone to answer a few questions.

You may be withdrawn from the study if you fail to meet inclusion criteria for the study.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date