Optimization of OnabotulinumtoxinA (BTX-A) Injection for the Treatment of Neurogenic Lower Urinary Tract Dysfunction

NCT06059066

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STUDY INFORMATION

Title of Study| Optimization of OnabotulinumtoxinA (BTX-A) Injection for the Treatment of Neurogenic Lower Urinary Tract Dysfunction

Principal Investigator|Rose Khavari, MD
Service Line/Department|Urology Department
Sponsor| NIH Office of the Director (Prime Sponsor), CAIRIBU (Direct Sponsor), Departmental Funds
Site Location | Houston Methodist Hospital, 6560 Fannin Street, Suite 2100, Houston, TX 77030

Key Information about This Research Study

You are being asked to participate in a research study. Participation is completely voluntary. It is your choice whether or not you take part in this research study. Your choice will in no way impact your access to medical care within the Houston Methodist. Participation in this study may or may not directly help you or others.

You are encouraged to ask any and all questions you have to the study team related to participating before agreeing to join a research study.

Why is this study needed?

You are asked to be in this study because you are scheduled to receive bladder Botox injections to symptoms of overactive bladder (OAB), which consists of symptoms such as urinary frequency, urinary urgency, urgency incontinence, and nocturia (having to void many times at night).

Although there is no one single way that Botox injections are given, normally Botox injections are mixed with saline and given in about 20-30 different injections in the body. This is called the “standard volume and number of injections” method and is the most commonly used method.

Another way of receiving Botox injections is to mix the Botox with a smaller amount of saline so the “dose” of Botox is higher and can be given with a fewer number of injections (about 5). This is called the “low volume, fewer injections” method. Although it is not a standard method, this method is used at Houston Methodist.

The goal of this research study is to compare the standard volume and number of injections method to the low volume, fewer injections method. Researchers want to learn if one method is better, the same, or worse than the other. Researchers also want to learn if patients prefer one method over another. It is hoped that this study can help to standardize the way Botox injections are given OAB.

What does participation in this research study involve?

Your active participation in this research will last about 6 weeks, though information from your medical record may be collected up to 1 year after you receive botox. During the study, you will be randomly assigned to a Botox injection method and then complete surveys about your experience with the procedure. Surveys will be completed the day of your procedure, and again approximately 4-6 weeks after the procedure.

Up to 78 participants will be enrolled in this study at Houston Methodist.

If you are a student, your decision not to participate or to withdraw from the study will not affect your grades or other academic standings at Houston Methodist. If you are an employee of the Houston Methodist, your decision not to participate or to withdraw from the study will not affect your employment at the Houston Methodist.

What are the risks and benefits of this research study?

Almost all research studies involve some risk. The risks of this study are minimal. These risks are described in detail later in this document.

There may be no benefit to you for taking part in this study. The injection methods being compared are the same as your standard of care, but if you are assigned to the low volume, fewer injections method, you may benefit by having fewer injections (which may be less painful or uncomfortable). Future patients may benefit from what is learned.

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

You do not have to be in this research study to get care for your incontinence. If you decide not to participate in this study, you have other choices. For example, you may choose to get the regular care described above for your condition. You may participate in a different study if one is available. These options may have risks. Discuss the possible risks and benefits with your study doctor.

The information below provides a comprehensive study description. Please read it carefully and ask any questions you may have before deciding to participate.

What if I am already participating in another study?

Are you currently enrolled in any other research studies? Please indicate "yes" or "no." If yes, please specify which study/studies: _____

If you answered yes, the Principal Investigator of this study may, based on the other types of studies you are participating in, decide that you cannot be in this research.

How is this research funded?

This research is being funded through an award called CAIRIBU, departmental funds and NIH is the primary sponsor for this study.

What happens if I say "yes, I want to be in this research"?

If you are found to be eligible to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 groups.

- **Group 1**: In Group 1, you will receive Botox injections into the bladder using the "standard volume and number of injections" method. This group will receive about 20 injections.
- **Group 2**: In Group 2, you will receive Botox injections into the bladder using the "low volume, fewer injections" method. This group will receive about 5 injections.

You will have an equal chance (50/50) of being assigned to either group. You will not know which group you are in, but your doctor will know.

Both groups will receive the same "dose" of Botox (about 200-300 units), but the Botox will be mixed with different amounts of saline. You will be given numbing medication before you receive the Botox injections.

You will sign a separate, standard consent form for the Botox injection procedure explaining how the procedure will be done and its risks.

Surveys and Data Collection

You will complete a survey about your symptoms, pain levels, and willingness to repeat the Botox injection procedure in the future. It should take about 5 minutes to complete. You will complete the surveys before your procedure (on the day of your procedure), and about 4-6 weeks after your procedure. The 4-6-week survey may be completed by phone, if you cannot come to the clinic.

Information from your medical record will also be collected as part of this study up to a year after the study conclusion.. This may include information about your medical history, treatment(s) received, and demographic information (such as age, sex, race, and so on).

Urine Collection

As part of your standard care, you will have urine collected for routine tests on the day of your procedure. As part of your participation in this study, the results of that urine test will be collected.

What are the risks and discomforts involved?

There are risks to participating in this research. The study doctor and study team will watch you to see if you are having any side effects related to your participation. Tell the study team as soon as possible if you experience pain or discomfort.

Your doctor will discuss with you the risks of receiving Botox injections into the bladder as part of your standard of care. There are no expected risks related to the **different methods of giving Botox injections.** There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

There is a risk of **loss of confidentiality**, meaning your information could become known to someone not involved in this study.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

What happens if I am injured or get sick because of this study?

If you have a research-related injury, treatment will be available. A research-related injury is an illness directly caused by the study procedure. You should contact the principal investigator of this study, Dr. Rose Khavari at 713-441-9118. These costs may be billed to your insurance. If you do not have insurance or if your insurance company refuses to pay, you may be expected to pay.

Houston Methodist and the study doctor do not generally provide funds or free medical treatment for injuries that result from taking part in this study. There are no plans to pay you for lost wages, disability, or discomfort. However, by signing this form, you have not given up any of your legal rights.

What if new information becomes available?

We will tell you about any new information developed during your participation in this research if the information could relate to your willingness to continue participating in this study.

Will being in this study cost me anything?

You and/or your insurance provider will be responsible for the cost of the routine clinic care, which includes Botox injection. The study team will review a list of procedures with you that show which are standard of care and which are research only. Unless a procedure is listed as 'research,' you should expect that you and/or your insurance company will be responsible for the payment of items and services. You will be responsible for your standard co-payments and co-insurance/deductibles.

If you have questions about the cost of participation, ask for more information before deciding to participate in the study.

Will I be paid or receive anything for being in this study?

We will pay you $150 total for participating in this study. Payment will be provided at the end of the study visit as a check. You will receive $100 at the Botox injection visit after completing all the research-related activities, and $50 will be given to you at the end of your follow-up visit after you answer the second set of surveys. If you choose to leave or we take you off the study before you complete the study visit, you will receive $100 after your Botox injection.

You may be asked for your social security number for payment purposes. It will not be used for any other purpose without your permission.

If you receive $600 or more during a calendar year from the Houston Methodist for participating in research, you will need to provide either your social security number or Individual Taxpayer Identification number (ITIN). If you do not have one of these, the study team will speak to you about your options regarding participation in the study. If you receive more than $600 in a calendar year for your participation in research, you may receive a 1099 for tax reporting purposes and Houston Methodist may report this to the IRS as income you have received.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records to people who have a need to review this information or as otherwise required by law. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information, including the IRB and other Houston Methodist representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who can access your name, address, phone number, and other information that can identify you.
We will remove identifiable information from the data we collect about you. After removing all the identifiers, we will place a code on the information. The code will be linked to your identity, but the link will be kept in a separate location from your study data. We will maintain your study data on encrypted computers, and access to the information will be limited to only members of the research team who need access to conduct the study properly. The information we send to the sponsor will not include information that directly identifies you. Instead, a code will be applied to the data, and the link between the code and your identity will be kept at the research site.

The study doctor and research team may publish the results of this research. However, they will keep your name and other identifying information confidential.

If you are or have been, a patient at a Houston Methodist facility, you will have a Houston Methodist medical record. We use an electronic medical record system known as Epic, which improves access to information necessary for your medical care. Epic will show that you are in a research study, and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in Epic. This includes explicitly investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well. Including this information in the electronic medical record system is intended only to give information to caregivers providing treatment for you while you are in this study.

This information will be available to Houston Methodist doctors, nurses, and other authorized staff who may not be part of the research team but who are involved in providing you medical care or who are otherwise allowed to access your information. If the study is related to your medical care, we may include the study-related information in your permanent hospital, clinic, or physician's office records.

The confidentiality of the results and other documents in Epic will be governed by laws, such as HIPAA, concerning medical records. We suggest that you tell any non-Houston Methodist doctors that you are in a

research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

What is the purpose of this part of the form?

State and federal privacy laws protect the use and disclosure of your Protected Health Information ("PHI"). Under these laws, your healthcare providers generally cannot disclose your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the Houston Methodist, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. We call these people and institutions "Providers" in this form.

What Protected Health Information will be used or shared?

You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be used or disclosed includes:

- Your past medical history;
- Medical information from your primary care physician;
- Images, videos, and other recordings of you that are taken as part of the study;
- All other medical information relating to your participation in the study such as test results, diagnostic images, and the medical care you receive as part of the study;
- Genetic or genomic data obtained by analyzing the biological samples you provided, if the consent document describes genetic analysis;
- Information relating to Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS");
- Information relating to the treatment for or history of drug or alcohol abuse; and
- Information relating to your mental or behavioral health and any psychiatric care.

This information may be disclosed electronically as part of your participation in this study. Any electronic disclosure will be in accordance with HIPAA and Texas laws.

Who may receive my Protected Health Information?

The following individuals may have access to or receive your PHI as a result of your participation in the study:

- Members of the research team
- Offices and committees responsible for the oversight of research

- NIH, CAIRIBU, and U.S. Office for Human Research Protections
- Other federal and state regulatory authorities including but not limited to the U.S. Food and Drug Administration (FDA), the U.S. Department of Health and Human Services, and the Texas Health & Human Services Commission
- Regulatory Authorities from other countries
- The study sponsor and the study sponsor's contractors or agents

Why will my Protected Health Information be used and disclosed?

- Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
- The research sponsor, its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in the first part of this document and for other activities related to the research. These activities include assessing the safety or effectiveness of the treatment that we are studying, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
- Houston Methodist's clinical trial organizations will use your information to review and support clinical trials at the Research Institute.
- Other Houston Methodist offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, and Compliance may use your information to ensure the study teams are performing the research correctly.
- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who must use your information to review or oversee this research and to review the data so they can decide whether to approve a new drug, device or other health care product for marketing.

What other information should I know?

1. Once the study team has disclosed your information to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your decision will not affect your right to other medical care.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you may write to the study doctor or to the Human Subjects Research Office at Houston Methodist Research Institute, 6670 Bertner Avenue, Houston, TX 77030, or you may call 346-356-1400.

4. If you revoke this Authorization, you will not be able to continue taking part in the research. The information collected prior to your withdrawal can still be used as described in this form.
5. While the research is in progress, you cannot access and read your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.
6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years, and it is not possible to know when they will complete the analysis.
7. A study team member will give you a copy of this informed consent /authorization after you sign it.
8. 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 this web site at any time.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

- To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
- To meet the requirements of the U.S. FDA;
- If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
- If information about you must be disclosed to prevent serious harm to yourself or others such as
- If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
- If it is used for other scientific research, as allowed by federal regulations protecting research participants.
- To Houston Methodist doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care and other health care operations.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide written consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.

Will information or leftover specimens be used for other research?

Information collected about you will be used for this research and may also be used for other research studies here at the Houston Methodist. There may also be collaborative research efforts with other entities, such as universities, the government, and private companies where we may share your information and specimens. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information came from. We will not ask for additional consent from you to use your information for the additional research.

What happens if I want to leave the study?

You will not lose any services, benefits, or rights you would usually have if you choose not to be in the study or if you leave the study early.

If you decide to leave the research, contact the study team so the investigator can work with you to create a safe plan for your withdrawal.

You may be asked why you are leaving the study and your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in "Contact Information."

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- Your health changes, and staying on the study is no longer in your best interest;
- You do not follow the study rules, or you no longer meet the requirements to be in the study; or The study is stopped by the sponsor or researchers.

Contact Information

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Study Doctor.

Study Doctor | Dr. Rose KhavarI
Phone Number | 713-441-9118

Houston Methodist's Office to help protect you in this Research Study is called Human Research Protections Office (HRPO). You are welcome to call HRPO if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Human Research Protections Office (HRPO) | 1-346-356-1400

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form, and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent/authorization form after I sign it.*

Signature of Participant	Printed Name	Date
Signature of Person Conducting Informed Consent Discussion	Printed Name	Date