Benaroya Research Institute

Intradetrusor Onabotulinumtoxin A (Botox) at the time of Transurethral Resection of the Prostate or Transurethral Waterjet Ablation of the Prostate for Mixed Lower Urinary Tract Symptoms

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

IRB Number: IRB24-069

PRINCIPAL INVESTIGATOR: Thomas W. Fuller, MD
Virginia Mason Franciscan Health
Department of Urology
1100 Ninth Ave C7-URO
Seattle, WA 98101
Work phone: 206-223-6772

SUPPORTED BY: Benaroya Research Institute

STUDY SUMMARY

The purpose of this study is to see if using Botox at the same time as transurethral resection of the prostate (TURP) or transurethral waterjet ablation of the prostate (Aquablation®) is effective for relieving overactive bladder symptoms, specifically for people who have benign prostatic hyperplasia (BPH) and signs of overactive bladder (OAB).

You are being asked to be in this study because you are scheduled to undergo a TURP or Aquablation® surgery. You are also scheduled to receive Botox at the same time as the surgery.

Using Botox at 100 units to treat overactive bladder is approved in the United States by the U.S. Food and Drug Administration (FDA). TURP and Aquablation® are standard of care surgical treatments for an enlarged prostate. There are currently no studies on the usage of receiving Botox while undergoing TURP or Aquablation®. We are doing this study to learn more about the outcomes of patients who receive Botox during one of these two surgeries.

If you participate in this study, you will be asked to fill out questionnaires about your overactive bladder symptoms both before and after your surgery. There will be two questionnaires prior to surgery, in which you will be asked about your overactive bladder symptoms and how those symptoms affect your quality of life.

Following surgery, you will be given more questionnaires during your standard follow-up visits. These questionnaires will be used to assess your overactive bladder symptoms and to ask about your quality of life following the procedure. They will be given on a four-week follow-up visit and at a 3-month follow-up visit. There will be four questionnaires per visit.

We think you will be in the study for a total of 4 months, or until your 3-month post-operative visit.

Filling out the questionnaires could lead you to feel uncomfortable or upset. You have the right to refuse to answer any questions.

There is a risk of loss of confidentiality of your information. You will read about the steps we take to help keep your information private and secure later in this form.

This study does not involve treatment for your BPH, or for side effects that may result from your TURP or Aquablation® surgery. Your alternative is to not be in the study.

If you agree to take part in this study, there will be no direct benefit to you. We hope the information learned from this study will benefit other people receiving TURP or Aquablation® surgery in the future.

Taking part in this study is voluntary, and you may choose not to take part or may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled outside of this research.

You are being asked to take part in this study because you are scheduled to have a procedure called transurethral resection of the prostate (TURP) or transurethral waterjet ablation of the prostate (Aquablation®) to treat your benign prostatic hyperplasia (BPH). This particular research in humans is designed by Thomas Fuller, MD and Cristina Palmer, DO, and is regulated by Benaroya Research Institute.

The following is a summary of the information you were given when this study was discussed with you. You may discuss this information and your decision with anyone you choose. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

WHY IS THIS STUDY BEING DONE?

Benign prostatic hyperplasia (BPH) is a condition in which the prostate gland is enlarged and not cancerous. People who have BPH may also have symptoms of overactive bladder syndrome (OAB) as a result of their condition. Some people who have BPH will undergo transurethral resection of the prostate (TURP) or transurethral waterjet ablation of the prostate (Aquablation®) to treat the condition. If you have overactive bladder, it is possible for those overactive bladder symptoms to get worse after TURP or Aquablation® surgery. These symptoms include worsening urgency and frequency of urination, which can be distressing.

One of the ways in which overactive bladder syndrome is treated is with Botox injected into the bladder. Injecting Botox into the bladder can help the bladder muscle relax, which can help with symptoms of overactive bladder syndrome.

Using Botox at 100 units to treat overactive bladder is approved in the United States by the U.S. Food and Drug Administration (FDA). Currently, there is no data on the use of Botox at the time of TURP or Aquablation® to help alleviate overactive bladder symptoms.

We are doing this study to see how overactive bladder symptoms are affected when Botox and TURP or Aquablation® are performed together.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 20 people will take part in the study at Virginia Mason.

WHAT IS INVOLVED IN THE STUDY?

Before Surgery

If you choose to participate and sign this consent form, you will be given two questionnaires prior to surgery. These questionnaires involve asking about your overactive bladder symptoms and how those symptoms affect your quality of life. You may choose not to answer any questions you don't want to. It will not affect your participation in the study.

Follow-up After Surgery

After your surgery, we will ask you to fill out more questionnaires. These questionnaires will be given to you during your standard follow-up visits to assess your overactive bladder symptoms and to ask about your quality of life following the procedure. They will be given on a four-week follow-up visit and at a 3-month follow-up visit. There will be four questionnaires per visit.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for a total of 4 months, or until your 3-month post-operative visit.

The researcher may decide to take you off this study if it is in your medical best interest or if you become unable to fill out pre- and post-operative questionnaires.

You can stop participating in the study at any time. If you decide to stop being in the study, please talk to the researcher and your regular doctor first.

If you leave the study, we will still use your information collected before your participation ended.

WHAT ARE THE RISKS OF THE STUDY?

Filling out the questionnaires could lead you to feel uncomfortable or upset. You have the right to refuse to answer any questions.

For more information about risks, ask the researcher or contact your study doctor at the telephone number listed on the first page of this form.

There is a risk of loss of confidentiality of your information. You will read about the steps we take to help keep your information private and secure later in this form.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will be no direct benefit to you. We hope the information learned from this study will benefit other people receiving TURP or Aquablation® surgery in the future.

WHAT OTHER OPTIONS ARE THERE?

This study does not involve treatment for your BPH, or for side effects that may result from your TURP or Aquablation® surgery. Your alternative is to not be in the study.

WHAT ARE THE COSTS?

Taking part in this study is not expected to lead to added costs to you or your insurance company. You will receive no payment for taking part in this study.

WHAT IF YOU GET INJURED BECAUSE YOU TOOK PART IN THIS STUDY?

It is important you tell your study doctor, Thomas Fuller, MD, if you feel you have been injured because of taking part in this study. You can tell the doctor in person or call him at 206-223-6772.

You will get medical care if you get hurt as a result of being in this study. Medical services will be offered at the usual charge and billed to your insurance. No funds have been set aside to compensate you in the event of injury. This does not limit your ability to seek compensation for study related injuries.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

You do not waive any of your legal rights by participating in this study. Taking part in this study is voluntary, and you may choose not to take part or may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled outside of this research. No matter what choice you make, the quality of care you receive at this institution will not be affected in any way.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

- For questions about study procedures, study costs, or to report a study-related injury, contact the researcher, Thomas Fuller, MD, at 206-223-6772.
- For questions about your rights as a research participant, contact the BRI Institutional Review Board (IRB) Manager at (206) 342-6916. The IRB Administrator manages the IRB, which is a group of people who review this research to protect your rights and welfare.

WHERE CAN I GET MORE INFORMATION?

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.

You will get a copy of this consent form.

HOW WILL MY IDENTIFIABLE INFORMATION BE USED?

Your information will be labeled with a code, not your name. The information you provide in this study will be used for the purposes described in this form only. It is possible that we might anonymize your information by removing identifiers in a way that would make it very hard for us or anyone else to identify your information as yours.

STORAGE OF YOUR INFORMATION FOR POTENTIAL FUTURE RESEARCH:

We may store your information to use for future research. The reason we wish to do this is to continue to look at the long-term outcomes of Botox and TURP or Aquablation®. For future research with your information, researchers might remove identifiers and the de-identified information might be used or shared with other researchers for future research without any additional consent from you. Findings or results from any testing or future research would not be reported back to you.

Will I be notified if my data result(s) in an unexpected or clinically relevant finding?

When data are collected and analyzed, there is the chance of finding something important or unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

The results from the data we collect in this research study are not the same quality as what you would receive as part of your health care. The data results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any important or unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

There are no plans to provide all participants with clinically relevant information from the research as a whole.

AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We are required by federal and state privacy laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to protect the privacy of your health information. By signing this form, you authorize the individuals and entities listed below to use and disclose your health information for the purposes of the research study described in this form and in the above Consent ("Consent"). If you do not sign this form, then you will not be able to participate in this research study.

WHAT IS PROTECTED HEALTH INFORMATION (PHI)?

PHI is information that is created or received by a health care provider, health plan, or health care clearinghouse that relates to your past, present, or future physical or mental condition; the provision of health care to you, or the past, present, or future payment for the provision of health care to you; and that identifies you or there is a reasonable basis to believe the information can be used to identify you.

PHI includes, but is not limited to:

- Health information from your existing or future medical records needed for this study as described in this form; ***and***
- Health information about you created during this study, as described above.

The health information that you authorize for disclosure includes, but is not limited to demographics information, results of physical exams and tests performed, histories and physicals, questionnaires, records of treatments and side effects of treatments.

You should have received a Virginia Mason Notice of Privacy Practices at the time of your first service delivery. Let us know if you would like an additional copy of the Notice. Please review the Notice carefully for additional information about your privacy rights related to your PHI.

WHO MAY USE AND DISCLOSE MY PHI?

Virginia Mason and its health care providers, including but not limited to its primary care providers, are permitted to disclose your PHI to the Principal Investigator and Sub-Investigators (collectively, "Researchers") listed in the Consent. The Researchers may also use and disclose your health information between each other and with the other individuals and entities listed in this Authorization.

WHAT MAY THE RESEARCHERS DO WITH MY PHI?

The Researchers will use your health information to conduct the research. As part of the research, they may disclose your information to certain individuals and entities. These individuals and entities who may receive your PHI include:

- The sponsor of this study, Thomas Fuller, MD, at Virginia Mason Franciscan Health, Department of Urology. The sponsor reviews the study and Researchers must disclose your health information with the sponsor.
- The Institutional Review Board (IRB) that approved this research, Benaroya Research Institute (BRI) IRB. The IRB reviews, audits, and monitors studies to protect the rights and safety of research participants.
- BRI Regulatory Compliance and Education Department in order to allow the Department to conduct routine internal quality reviews audits and monitor visits of the study and patient records.
- BRI coordinators, managers and assistants for the purposes of research study administrative and related support, including but not limited to pre-screening and follow up for research participants, and reporting to sponsors and government agencies.

HOW WILL MY HEALTH INFORMATION BE KEPT PRIVATE?

All efforts will be made to keep your personal information confidential as required by law. We may use and disclose your health information as permitted or required by law.

Once your PHI is disclosed to a third party, that party may share it with someone else and the HIPAA protections may no longer protect it; however, other privacy protections may still apply.

If research findings are published from this study, they will not identify you unless you consent to the use of your identifiable information in writing.

HOW LONG WILL THIS AUTHORIZATION LAST?

This Authorization will expire when the use and sharing of your PHI is no longer necessary for the research purposes described in this form, or, if you change your mind and revoke your authorization in writing before then. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be completed.

WHAT HAPPENS IF I WANT TO REVOKE MY AUTHORIZATION?

You may change your mind and revoke (i.e., take back) this Authorization at any time. This request must be made in writing to the investigator Thomas Fuller, MD, at the address listed on page 1 of the Consent. However, even if you revoke this Authorization, the Researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you withdraw your Authorization, you will not be allowed to continue in this research study.

PARTICIPANT'S CONSENT AND AUTHORIZATION

I have read and been given a chance to ask questions about this consent form and HIPAA authorization. I agree to take part in this study and agree to the use and sharing of my information as described in this form. I will receive a signed copy of this consent form and HIPAA authorization.

PARTICIPANT'S SIGNATURE **PARTICIPANT'S NAME** (print) **DATE**

CERTIFICATE OF PERSON OBTAINING CONSENT:

I have provided an explanation of the above research study and have encouraged the subject to ask questions and request additional information regarding the study and possible alternatives. A signed and dated copy of this consent form will be given to the subject.

SIGNATURE OF PERSON OBTAINING CONSENT **NAME OF PERSON OBTAINING CONSENT** (print)

DATE