19-005486

Pilot Study for the Treatment of Papillary Thyroid Carcinoma with Radiofrequency Ablation

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MAYO CLINIC

Name and Clinic Number

Approval Date: **February 28, 2020**
Not to be used after: **February 27, 2021**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Pilot study for the Treatment of Papillary Thyroid Carcinoma with Radiofrequency Ablation

IRB#: 19-005486

Principal Investigator: Marius Stan, M.D. and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to evaluate the safety and efficacy of Radiofrequency ablation (RFA) for treatment of papillary thyroid carcinoma. You have been asked to take part in this research because you have previously been diagnosed with papillary thyroid carcinoma and you have elected not to have this lesion treated with surgery.

What's Involved	Study participation involves a half-day at the clinic for the RFA procedure. Following discharge, phone communication will be conducted periodically for up to 3 months and face-to-face visits for long term follow-up for up to 18 months.
Key Information	Risks associated with RFA are similar to those of thyroid surgery though much less frequent to occur than after surgery. The procedure is offered free of cost and select laboratory tests are paid by research. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Marius Stan, M.D. Phone: 507-284-2463 **Co-Investigators:** Matthew Callstrom, M.D. Phone: 507-266-4532 Robert Lee, M.D. Phone: 507-255-1222 **Study Team Contact:** Vishakantha Murthy, Ph.D. Phone: 507-255-8112 **Institution Name and Address:** Mayo Clinic 200 First Street SW, Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

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Other 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.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have previously been diagnosed with papillary thyroid carcinoma and you have elected not to have this lesion treated with surgery.

The plan is to have about 5 people take part in this study.

Why is this research study being done?

The purpose of this pilot study is to evaluate the safety and efficacy of Radiofrequency ablation (RFA) therapy for treatment of papillary thyroid carcinoma.

Information you should know

Who is Funding the Study?

This study is being funded by the Richard F. Emslander Career Development Award in Endocrinology and Nutrition at Mayo Clinic.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be actively involved in the study for up to 6 months, and long term follow-up will last up to 18 months. Your medical records may be accessed for up to two years after completing the study in order to collect additional clinical or follow-up information.

What will happen to you while you are in this research study?

Once enrolled, you will be scheduled for RFA in the procedure room. You will need to be fasting for this procedure. RFA is carried out using ultrasound guidance and lasts for about 30 – 45 min and will be performed by a radiologist. You will be sedated with general anesthesia during the procedure.

Upon completion of the procedure, you will be monitored for additional 3 hours in Post Anesthesia Care Unit (PACU) and released home thereafter. You will also be asked to fill-in a pain questionnaire to assess any level of pain or discomfort post RFA procedure.

You will be contacted by phone in the first 72 hours to assess for the presence of any adverse effects related to the procedure. Moving forward, you will be contacted in a similar manner approximately every 2 weeks for the first 3 months for the purpose of detecting any adverse effects. You will have a face-to-face visit 1 month after the procedure for safety assessment as well. During this visit you will provide blood sample for laboratory tests (Calcium and thyroid tests TSH, T3, T4, and Tg); costs for these tests are covered by research. Next face-to-face visit will happen at 3 month after the procedure; at this visit you will provide a small volume of blood to test thyroid receptor antibody, the cost of which is covered by research. Further in the process, you will be monitored clinically for up to 18 months post RFA procedure.

Note: In addition, , in the procedure room, a small volume of blood (one teaspoon) will be obtained just before the RFA procedure and soon after RFA procedure to test the biological activity of thyroid hormones in the research laboratory.

What are the possible risks or discomforts from being in this research study?

Risks associated with RFA: many are similar to those of thyroid surgery though much less frequent to occur than after surgery. The risks depend on the area treated but include skin burn, bleeding, infection, numbness, weakness, nerve injury, hoarseness, lung collapse (pneumothorax), and pain. Some of the risks and complications may require hospitalization and surgery.

Anesthesia risks: All types of anesthesia involve risk due to unexpected reactions or complications. Potential complications include damage to teeth, mouth or throat, allergic reactions, pneumonia, inflammation of the veins, nerve injury, or paralysis, damage to the heart, liver, kidney or brain, infection, or the possibility of death.

Blood draw risk:
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or very rarely, infection at the site of the needle stick.

Note: Pregnant women will not be allowed to enroll on this study. Please tell your study doctor if you are pregnant or think you might be pregnant.

If you are a female, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.

You are advised not to get pregnant owing to your current health condition (papillary thyroid carcinoma); however the RFA procedure is not known to have any negative impact on fertility or the outcome of a subsequent pregnancy.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. However, if RFA therapy is effective we expect that you might be able to avoid thyroid surgery and the need for therapy with thyroid hormone.

What alternative do you have if you choose not to participate in this research study?

Most patients with papillary thyroid carcinoma proceed to have surgical treatment. Some are placed under medical observation when surgery is not considered a necessary treatment (e.g. small cancers < 10 mm, called microcarcinomas). You don't have to be in this study to receive these treatments for your condition.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedure which are done just for this research study. These tests are procedures are:

- Radiofrequency Ablation
- Baseline laboratory tests if not in the medical record
- Laboratory tests (Calcium, Thyroid tests - TSH, TT3, FT4, thyroglobulin, thyroglobulin antibody and TRAb at one month post RFA visit and TRAb at 3 months post RFA visit)
- Research laboratory T3 and T4 analysis
- Pregnancy test if applicable

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- Exams and laboratory tests (Calcium, Thyroid tests - TSH, TT3, FT4, thyroglobulin, thyroglobulin antibody) at 3, 9 and 18 month as clinically indicated

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will be paid $300 upon completion of the study ($150 for completion of RFA procedure and remaining amount will be $50 for each follow-up visits).

Will your information or samples be used for future research?

The results of the ultrasound and the laboratory tests performed as part of this study will be available in your medical record. There will not be storage of any of your samples after the study is completed.

Your information or samples collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Data will be entered into a separate database which will not contain any identifiers. All information, research data, and related records will be coded, and this code will be used on all documents to prevent subject identification. The principal investigator will ensure that this document is password-protected, and that both the document and the password are kept in a secure, private hard-drive. This document will be destroyed at the end of the research study. You will not be identified in any publications or presentations that result from this study.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and

why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

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Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

I have explained the research study to the participant.

- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature