ClinicalTrials.gov ID: NCT03040622

Unique Protocol ID: 16-2583
Official Title: The Evaluation of Thrombogenecity in Patients Undergoing WATCHMAN Left Atrial Appendage Closure (TARGET-WATCHMAN) Trial

Brief Title: TARGET-WATCHMAN

Document dates:
Protocol: January 5, 2018
Informed consent: February 9, 2018

RESEARCH CONSENT
Date Approved: February 9, 2018
Inova IRB: Joanne Muratori, IRB Coordinator
IRB File # 16-2583

Informed Consent for a Research Study

Study Title:	The evaluation of thrombogenicity in patients undergoing WATCHMAN left atrial appendage closure trial
Sponsor:	Boston Scientific, Inc.
Principal Investigator:	Paul Gurbel, M.D.
Co-Investigators:	Shahram Yazdani, MD; Haroon Rashid, MD; Matthew Sherwood, MD; Robert McSwain, MD; Adam Strickberger, MD
Site of Investigation:	Inova Heart and Vascular Institute
Study Related Contact Information:	(703) 776-3567 (During Business Hours) (703) 776-4001 (After Business Hours)

Introduction
You may be eligible to take part in a research study. This research consent form gives you important information about the study. It explains why this research study is being done, what is involved in participating in the research study, the possible risk and benefits of participation, choices for participation and your rights as a research participant.

Please take your time to review this information carefully. You may also wish to talk to others (for example, your family, friends, or other doctors) about your participation. The decision to participate is yours. You may leave the study at any time without losing any benefits you would have normally received. If you decide to take part in the study, you will be asked to sign and date at the end of this form. We will give you a copy of the form so that you can refer to it while you are involved in this research study. We encourage you to ask questions now and at any time in the future.

You should know that Inova investigators are being paid by Boston Scientific, Inc. to conduct this research study.

What if I am already participating in another study?
Are you already participating in any other research studies? Yes ☐ No ☐
If yes, please state which study (ies) _____

While participating in this study, you may not take part in any other research study without approval from the principal investigator.

RESEARCH CONSENT
Date Approved: February 9, 2018
Inova IRB: Joanne Muratori, IRB Coordinator
IRB File # 16-2583

Why is this study being done?
Atrial fibrillation is a medical condition where the heart beats irregularly. Normally, the heart contracts and relaxes to a regular beat. In atrial fibrillation, the upper chambers of the heart (atria) beat irregularly (quiver) moving blood into the ventricles (lower chambers of heart). The irregular heartbeats can make the heart work ineffective causing symptoms such as dizziness and fainting. The irregular heartbeats can also cause blood to collect in the heart and potentially form a clot, which can travel to the brain and cause a stroke. Therefore, patients with atrial fibrillation are prescribed blood thinners (anticoagulants and anti-platelet medications) to prevent the formation of blood clots and stroke. Blood thinners do not really thin the blood; they reduce the formation of blood clots. Anticoagulants, such as warfarin (also called Coumadin), lengthen the time it takes to form a blood clot. Antiplatelet drugs, such as aspirin and clopidogrel (Plavix), prevent platelets from clumping together and forming blood clots. Platelets are tiny blood cell fragments that circulate through the bloodstream. Any alternations in platelet function may cause abnormal bleeding.

People with atrial fibrillation face lifelong use of blood thinners and the associated risk of bleeding. The WATCHMAN device is a permanent implant placed close to the left atrium of the heart. It works by blocking a small structure in the left atrium of the heart from filling with blood and forming harmful blood clots. The WATCHMAN implant is proven to reduce the risk of stroke in patients with atrial fibrillation (not caused by valve problems) who need an alternative to long-term use of blood thinners.

After a successful implantation of the WATCHMAN device, patients are prescribed warfarin for 45 days. After 45 days, a procedure called transesophageal echocardiogram is done to check for any clots in the left atria. If no clots are found, warfarin is routinely discontinued and patients are prescribed a combination of aspirin and clopidogrel for 6 months, and then discontinued.

You are invited to participate in the study because you are scheduled to have a WATCHMAN device implantation procedure for your atrial fibrillation. So far, no data exists on whether patients who have a WATCHMAN implant, have differences in their ability to form blood clots after the procedure.

The purpose of this study is to determine if there are specific biomarkers (substances in the blood) that can predict the risks of developing blood clots after undergoing a WATCHMAN device implantation. The findings of this study may help guiding physicians on how long to prescribe anticoagulants or antiplatelet medications to each individual patient who has undergone a WATCHMAN device implantation.

How many people will take part in this study?
Approximately 40 people are expected to be enrolled in this study at Inova Heart and Vascular Institute.

You may qualify to participate in the study if you are 18 years of age and older and are scheduled for a WATCHMAN device implantation procedure.

What is the usual approach to my atrial fibrillation?
You will receive the standard treatment and procedures for atrial fibrillation, which may include a WATCHMAN device implantation, even if you decide not to participate in the study. If you decide to take part in the study, there will be no changes to the standard of care for your atrial fibrillation.

What other choices do I have if I do not take part in this study?
This study is designed for research purposes only and is not intended to treat a medical condition. Your alternative is not to participate in the study. You may choose to participate in another study, if one is available.

How long will I be in this study?
If you decide to participate, you will be in this study for 12 months.

What will happen if I take part in this research study?
Most of the exams, tests and procedures you will have are part of the usual approach for your atrial fibrillation and may be done even if you do not join the study. However, there are some additional tests that you will need to have if you take part in the study. If you agree to participate, you will be asked to do the following:

Before procedure:
Prior to WATCHMAN implantation procedure, you will:

- Provide informed consent and demographic information (sex, date of birth, race, ethnicity);
- Provide your complete medical and surgical history (including any allergies, tobacco use);
- Provide your current medications (including vitamins, over-the-counter drugs and herbal supplements);
- Have a physical exam and your vital signs (blood pressure and heart rate) checked
- Have your height and weight measured;
- Provide blood (approximately 4 teaspoons) and urine samples for platelet function and biomarkers testing prior to procedure. Biomarkers are substances in the blood that can determine a person's risk for certain disease.

WATCHMAN implantation procedure
Your doctor will use the current standard of care guidelines, your medical condition, and the local practices at the Inova Heart and Vascular Institute to perform your WATCHMAN device implantation procedure.

Immediately after procedure:
After the procedure, you will be observed in the hospital. Your vital signs will be monitored, ECG (electrocardiogram) done, and blood sample may be obtained for routine laboratory tests. These procedures may be performed if needed as part of your routine care. If the WATCHMAN device implantation procedure is successful, you will be asked to provide the following as part of this study:

RESEARCH CONSENT
Date Approved: February 9, 2018
Inova IRB: Joanne Muratori, IRB Coordinator
IRB File # 16-2583

- Blood (approximately 4 teaspoons) samples for platelet function and biomarkers testing;
- Information about any side (bad) effects you may have experienced after the procedure;
- Any changes in the medications you are taking.

Follow-up outpatient visits

The study team will follow-up with you at the time of your routine clinical visits and TEE procedures scheduled approximately 45 days, 6 months, and 12 months after you received the WATCHMAN device implant. During these visits, you will be asked to provide the following as part of this study:

- Blood (approximately 4 teaspoons) and urine samples for platelet function and biomarkers testing;
- Information about any side (bad) effects you may have experienced after the procedure;
- Any changes in the medications you are taking.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that you may:

- Lose time at work or home and spend more time in the hospital or doctor's office than usual
- May be asked sensitive or private questions which you normally do not discuss
- The most important non-medical risk is the disclosure of your protected health information (PHI). PHI is any health information that is collected about you, including your history and new information collected during this study. You will have an opportunity to review the ways in which your PHI may be used and disclosed in the authorization section of this form that begins on page 8.

There is also a risk that you could have side effects.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.

Related to study procedures

Needle sticks used to get your blood samples may cause some discomfort, pain, bleeding or bruising at the site where the needle is inserted, although this is generally minor and resolves within a few days. You may experience light-headedness and sweats. Rarely, fainting and a

decrease in blood pressure can happen. There is a very small risk that a nerve could be damaged during insertion of a needle, however, the site will be carefully chosen to minimize this risk. Nerve damage may continue, but usually resolves within 6-12 months.

There might be risks that are unknown at this time. You should talk to your study doctor about any side effects that you have while taking part in the study.

Are there benefits to taking part in this study?
Taking part in this study may or may not make your health better. We hope the information learned from this study will benefit others in the future.

Can I stop being in the study?
Yes. You can decide to stop at any time. It is important to tell the study doctor if you are thinking about stopping so any risks from the study procedures can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Tell the study doctor if you are thinking about stopping or decide to stop. He will tell you how to stop safely and will work with you to obtain a written confirmation of your decision to take back your authorization.

Your participation can also be stopped without your approval by your study doctor or the Institutional Review Board (IRB – hospital committee that reviews and approves research).

The study doctor may decide to take you off this study for any of the following reasons:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor

What are my rights if I take part in this study?
Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. A member of the study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you would like more information about your rights as a participant in a research study, contact: Inova Health System Institutional Review Board (IRB) at (703) 776-3167. The Inova Health System IRB may contact you by mail or telephone to find out if you were satisfied with your study participation.

What are the costs of taking part in this study?
It is anticipated that there will be no additional cost to you for participating in this study. The standard of care tests and procedures that you are receiving and continue to receive during the study will be charged to you or your insurance company as usual (including any coinsurance and

deductibles). This includes the procedures, testing, medications and hospitalization related to the WATCHMAN implantation procedure, post-procedural care, and follow-up items or services.

The study doctor's visits, study procedures and laboratory tests that are being performed only because you are taking part in this study and would not otherwise be part of your routine care will be provided at no cost to you.

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your heart disease in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. You may be responsible for any co-payments and deductibles that are standard for your insurance charges.

Will I be paid for taking part in this study?
You may receive up to $75 for your participation in the study. You will be reimbursed $25 for each follow-up visit completed at the study site (at 45 days, 6 months, and 12 months) to help cover your expenses related to those study visits, such as transportation, parking, and meals.

What if I am injured because I took part in this study?
In the event that you believe you have been injured because of taking part in this study, it is important that you call your study doctor. You can call Dr. Paul Gurbel, principal investigator, at (703) 776-3567 during business hours, or (703) 776-4001 after business hours and he will review the matter with you. Inova Health System and the study doctor do not provide funds or free medical treatment for injuries that result from taking part in this study. However, in the event of injury resulting from this research, medical treatment is available.

You and/or your health plan will be billed for the cost of this care. If your insurance does not pay for your care, or pays only a portion of the cost of such care, you may be billed for any unpaid amounts.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study. No funds have been set aside by Inova Health System to repay you in case of injury.

You are not waiving any legal rights because of your participation in this study.

Will my medical information be kept private?
We will keep your records private to the amount allowed by law. Research records are stored and kept according to legal requirements. You will not be identified in any reports or publications about this study. However, certain people and groups will have access to your research and medical records. The sponsor of the study will look at your research and medical records. The Inova Health System Institutional Review Board (IRB) and federal and state agencies that have authority over the study may look at your research records. Members of the study staff will also have access to your research records. Additional groups, explained in the authorization section beginning on page 8, may also have access to these records.

Who can answer my questions about the study?
You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor Dr. Paul Gurbel at (703) 776-3567.

Where can I get more information?
A description of this clinical trial will be available on 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.

RESEARCH CONSENT
Date Approved: February 9, 2018
Inova IRB: Joanne Muratori, IRB Coordinator
IRB File # 16-2583

Signature Page

As a member of the research team, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent*	Printed Name	Date

You, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and you have read this consent and received a copy of this consent, including the section regarding authorization to use and disclose protected health information. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to give your consent to participate in this research study.

You are free to withdraw from the study at any time and you do not have to say why you no longer wish to participate. You will notify Dr. Gurbel, if you are leaving the study because of any side effects you might experience. This withdrawal will not in any way affect your future treatment or medical management. You agree to cooperate with Dr. Gurbel and the research staff and to inform them immediately if you experience any unexpected or unusual symptoms.

Signature of Subject	Date

Printed Name of Subject

Signature of Legally Authorized Representative	Date

Printed Name of Legally Authorized Representatives and Relationship to Participant

**The person conducting the informed consent discussion has signed above as witness. The following witness lines may be left blank, unless an impartial witness is required.*

Signature of Witness	Printed Name of Witness	Date