**UNIVERSITY OF CALGARY**

**CONSENT TO PARTICIPATE IN RESEARCH**

**Title:** Strategies for catheter ablation of persistent atrial fibrillation: a randomized, comparative study:

 STAR AF III

**Sponsor/Funder:** The Research Institute of the McGill University Health Centre (RI-MUHC), Montreal, Quebec, Canada

**Investigators:** Dr. Carlos Morillo (Primary Investigator)

 Dr. George Veenhuyzen Dr. Jacques Rizkallah

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 Dr. Erkan Ilhan Dr. Stephen Wilton

**INTRODUCTION**

Dr. Carlos Morillo andassociates from the Cumming School of Medicine at the University of Calgary are conducting a research study. We are inviting you to take part in this research project because your doctor recommended that you undergo an ablation procedure to treat your persistent atrial fibrillation. You are entirely free to accept or refuse to participate. Taking part in several research projects at the same time may be dangerous. If you are already taking part in a clinical study, please notify the study doctor.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form

You are being asked to participate in this research study because you have an arrhythmia called atrial fibrillation. Atrial fibrillation is a rapid and irregular cardiac rhythm in the upper chambers of your heart called the atria. Your doctor has referred you for a catheter ablation procedure to treat your atrial fibrillation. The procedure is presently performed in many hospitals and is not experimental. Different ablation strategies have been developed to treat atrial fibrillation. A virtual positioning system similar to a GPS (Global Positioning System) will be used to help your doctor to follow the position of the catheter(s) in your heart during the procedure.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to collect information to assess the safety and success of three different ablation strategies for treating atrial fibrillation. None of which are experimental, and commonly used in clinical practice. This study will record the recurrence of atrial fibrillation after the ablation procedure for each of three techniques.

***The three ablation strategies in this study are:***

* 1- targets the tissues around the pulmonary veins (blood vessels that bring blood from the lungs to the heart) where the “triggers” of atrial fibrillation could be located (called “**pulmonary vein isolation**”).
* 2- combines the pulmonary vein isolation described above and “**linear ablation”** where regions of your atrium are electrically isolated from each other by tissue burned in a line.
* 3-combines the pulmonary vein isolation technique (1) and targeted ablation to tissue called "**fractional potentials:** “areas in your heart where the electrical signals are fastest, and we think impact your AF episodes.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY, HOW LONG WILL I PARTICIPATE?**

The study will include 600 patients from approximately 35-40 centers worldwide. Your participation in this study will last approximately 20 months. We hope to enrol 50 patients here at the University of Calgary/Foothills.

**WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

Your participation in this study consists of 3 phases; screening/randomization, ablation procedure and follow-up period. Below are details of each phase.

Screening/Randomization Visits

If you agree to participate in this study, you will sign this consent form. The research team will then consult your medical records and will collect information about your demographics, your medical history, your health, the medications you are taking, and any tests that you had before your ablation procedure. This information will be accessed by the study team through the Alberta NetCare System (a Province wide database containing your health records).

You will undergo a complete physical examination and a 12-lead electrocardiogram (ECG), to measure the electricity of your heart. You will also be asked to complete two quality of life questionnaires which should take about 5 minutes each to complete. You do not need to answer any questions which make you uncomfortable.

You will be “randomized” (like the flip of a coin) to one of the 3 ablation strategies described on page 1. You have a 33.3% chance of each technique.

If you are assigned to one of the groups of participants for whom the atrial fibrillation ablation will be done by combining two ablation techniques (# 2 & 3), the procedure time will be lengthened by approximately 30 minutes compared to the group of participants who will undergo procedure technique #1.

Before the ablation procedure, blood thinning medications, or an anticoagulant will be prescribed to you for a period of at least 4 weeks. If you do not receive this type of medication or you miss doses during this period, additional tests may be done to make sure there are no clots in the atria of the heart, as recommended by your doctor.

Antiarrhythmic drugs will be stopped few days before the ablation procedure, with the exception of amiodarone which, if you take it, will be stopped more than 4 weeks before the procedure.

Ablation Procedure

The ablation procedure will be performed according to current practices at the Foothills Hospital and based on the group you have been assigned to. We may use deep, conscious sedation (you are awake but drowsy) or general anaesthesia for your procedure. Once the procedure is completed, you will be monitored in the hospital for 4 to 6 hours, and discharged home the same day according to usual practice.

After you are discharged from the hospital, you will be asked to remain on your oral anticoagulation medication for at least 3 months after your ablation.

Your doctor may have you continue antiarrhythmic medications for the first 3 months after the ablation but these medications should be stopped after 3 months. Check with your study staff if you have questions about any of your medications before or after your procedure.

The research team will provide you with a small portable heart monitoring device called “Kardia” by a company called AliveCor which links with your smart phone or tablet to record your heart rhythm. The instructions for use will be explained to you by the research team. You will keep the device for during your entire participation in the study (~18months).

* If you have symptoms of atrial fibrillation, you will need to record your heart rate using the Kardia device and report it to the research team.
* If you have ***NO*** symptoms of atrial fibrillation, you will be asked to make a recording with your device every week and to send these recordings to the research team by email until the end of your participation in the study (about 18 months).

**Follow-up Visits**

You will be requested to come to the clinic for short follow up visits at 3, 6, 9, 12 and 18 months following your ablation. These visits will include:

* Vital signs, ECG
* Review of changes to your health and medications
* 2 Quality of Life questionnaires (at 12- and 18-month visits only).
* 24 hour holter monitor (Applied at and returned to a hospital or clinic, depending on availability)

If you have a recurrence of atrial fibrillation symptoms, it is possible that your doctor will recommend a repeat ablation procedure, using the same technique as the first ablation. At the end of the study, you will continue to be followed by your treating physician as per usual care.

**WHAT ARE THE RISKS?**

The three ablation procedures performed in this study are standard treatment methods and not experimental. There are additional risks when a combination of two techniques are used as the time of procedure will be longer by approximately 30 minutes, and more ablations will be done. No additional x-ray time is required for the additional procedures. Specific risks are below.

Ablation

Your doctor will review the risks of the ablation procedure before you sign the separate consent. The following risks are associated with the procedure:

* Occurrence of abnormal rapid heart rhythm from the upper chamber : Atrial tachycardia or Atrial Flutter, which may require additional medication or electrical conversion ≤15%
* Bleeding or infection where the catheter enters the skin <2%
* Creation of a hole in your heart muscle which could require urgent drainage or surgery<1%
* Narrowing of the blood vessels that brings blood back to your heart causing permanent shortness of breath <1%
* Stroke <1%
* Damage to the esophagus, or food pipe, which lies right behind the heart causing small connection between the heart and the esophagus, called a fistula, this complication severe but rarely seen <0.25%
* Injury to the phrenic nerve (the nerve to the diaphragm or breathing muscle) <4%

Questionnaires

You might find the interviews and questionnaires distressing or tiring. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

COVID 19 Related Risks

As some of visits for this study must be done in person to allow for physical examinations, application of a Holter monitor and ECGs, there is an added risk of you being exposed to COVID 19 from other people within the facility or by use of public transit to attend your appointment. We have several measures in place to reduce this risk as much as possible including screening each patient who attends our facility, use of PPE for all staff and patients, restrictions on the number of people allowed within the space, enhanced general cleaning procedures and sanitization of any space a patient occupies immediately following their visit.

**ARE THERE ANY REPRODUCTIVE or BREASTFEEDING RISKS?**

The catheter ablation procedure may be harmful to a fetus. For this reason, women who are pregnant will not be enrolled in this study. A pregnancy test will be required for women of child-bearing potential. In the event of pregnancy, or suspected pregnancy, you must tell your study doctor immediately. Your study participation may be stopped in order to avoid unknown risks to you, the fetus or infant.

**ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?**

You may personally benefit from your participation in this research project, but this cannot be guaranteed. However, the results obtained will contribute to furthering scientific knowledge in this field.

**WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?**

If you choose not to participate in this study, you will not be limiting your access to treatments available to manage your heart condition. You have the choice not to participate in this study. If this is the case, your study doctor will discuss other alternatives with you.

**CAN I STOP BEING IN THE STUDY?**

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from this project at any time, without giving any reason, by informing the research team. Your decision not to participate in this research project, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the teams providing them. However, before your withdrawal from this research project we suggestthat you return to the clinic for a final evaluation, for safety reasons.Any new findings during the course of the project that could influence your decision to stay in this project will be shared with you quickly, and you might be requested to sign an updated version of this document.

# **CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?**

Dr.Morillo, the Research Ethics Board, or the sponsor may end your participation without your consent. This may happen if new findings or information indicate that your participation is no longer in your best interest, if you are not following the study instructions, or if there are administrative reasons to terminate the project.

# **WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?**

During the study, the researchers could learn something about you that they didn’t expect. For example, the researchers may find out that you have another medical condition. The researchers will share these results with you. You will be helped with arranging appropriate follow up and care.

# **WITHDRAWAL OF STUDY DATA**

If you withdraw or are withdrawn from the project, the information and material already collected during this project will be retained, analyzed or used to ensure the integrity of the project.

**WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?**

You will not be paid to participate in this research study. The cost of parking will be paid for any hospital visits related to the study.

# **WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?**

During your participation in this research project, Dr Morillo and the research staff members will collect information in a study file about you which is required to meet the scientific goals of this research project.

This may include information from your medical chart concerning your past and present state of health, your lifestyle, as well as the results of all tests, exams, and procedures that will or have been performed.

You will use the Kardia App after creating a “dummy” account (using a generic email and birthdate) sharing only your study ID number . Data from recordings you make with the Kardia device will be sent to AliveCor, [Amazon Web Services (AWS)] and will be stored on a protected web platform for the length of study for the exclusive objectives of this project, and then they will be transferred in the sponsor records, as the other research data. You will only be identified by your anonymous study ID number on this device as well as the online storage platform. All the information collected will remain confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by Dr Morillo’s staff in a locked office.

Dr. Morillo’s study staff will forward your coded data to the sponsor or their representatives for storage and analysis. The sponsor may share the coded data with its commercial partners. However, the sponsor and its international partners are required to respect the confidentiality rules in effect in Canada.

The research data may be published or shared during scientific meetings; however, it will not be possible to identify you.

For monitoring, control, safety, and security purposes, your study file may be examined by a person mandated by regulatory authorities, such as Health Canada as well as by representatives of the sponsor, the institution, or the Research Ethics Board. All these individuals and organizations must follow strict privacy rules.

You have the right to consult your research file in order to verify the information gathered, and to have it corrected if necessary.

# **HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?**

This research data will be stored for 15 years by the study staff and the University of Calgary.

**IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?**

In the event that you suffer injury as a result of participating in this research, appropriate medical treatment will be provided. No compensation will be provided to you by the Research Institute of the McGill University Health Centre (RI-MUHC), the University of Calgary, Alberta Health Services or the Researchers. The study doctor and the University of Calgary still have their legal and professional responsibilities. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

The sponsor of this clinical trial has taken out insurance that covers its civil responsibility for any possible harm and injury that could be inflicted, as well as the study doctors taking part in the study.

# **WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

**The Research Team:**

You may contact Dr Morillo at 403-210-2670 or 403-210-6047 with any questions or concerns about the research or your participation in this study.

**Conjoint Health Research Ethics Board (CHREB):**

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

**Public Information about this Study:**

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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 website at any time. This project’s registration number is NCT 04428944.

# **HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?**

After the completion of the study, you can receive information on the results obtained in the study upon request. Results will also be posted on the above clinicaltrials.gov website.

# **WHAT ARE MY RIGHTS/RESPONSIBILITIES IF I TAKE PART IN THIS STUDY?**

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

* You have a right to have all of your questions answered before deciding whether to take part.
* Your decision will not affect the standard medical care you receive
* If you decide to take part, you may leave the study at any time.

It is important to remember the following things during this study:

* Ask your study doctor or study team if you have any questions or concerns.
* Tell your study doctor or study team if anything about your health has changed.
* Tell your study doctor or study team if you are or suspect you may be pregnant.
* Call the study doctor if you experience any side effects, even if you are unsure whether it has anything to do with this study.

I understand that I am being asked to participate in a research study about atrial fibrillation.

* This study was explained to me by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* I have read, or someone has read to me, each page of this Consent Form.
* All of my questions have been answered to my satisfaction.
* If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
* I voluntarily agree to participate in this study.

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| In the unlikely event of my death during participation in this research project, I authorize the research team to obtain a copy of my medical chart at any hospital or long-term care facility if they make such claim. This could include a copy of my records in emergency care unit or other clinical department. Information can be shared with the sponsor. | [ ] I accept | [ ] I refuse |

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| It is important that your family doctor know that you are in a research study, as you will be taking a treatment which could affect your health. I authorize the study doctor to inform my family physician about my participation in this project. Name and address of family physician :  | [ ]  I consent | [ ]  I refuse |

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| In the event that the researchers discover something about me, I consent that the study team may share these findings with me | [ ]  I consent | [ ]  I refuse |

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care.

If you have further questions concerning matters related to this research, please contact: Dr. Carlos Morillo (403) 944-2670 or Jennifer McKeage (403) 210-6047

If you have any questions concerning your rights as a possible participant in this research, please contact The Chair of the Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.

**SIGNATURE OF STUDY PARTICIPANT**

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Name of Participant

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Signature of Participant Date

**SIGNATURE OF THE PERSON OBTAINING CONSENT (Investigator or Delegate)**

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Name of Person Obtaining Consent Contact Number

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Signature of Person obtaining consent Date

**SIGNATURE OF THE WITNESS**

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Name of Witness

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Signature of Witness Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

 A signed copy of this consent form has been given to you to keep for your records and reference.