**TITLE:** STereotactic Arrhythmia Radioablation for Ventricular Tachycardia

Management (STAR VTM)

**SPONSOR: Dr. Vikas Kuriachan, University of Calgary**

**FUNDER:** Libin Cardiovascular Institute of Alberta

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**INTRODUCTION**

Dr. Vikas Kuriachan andassociates from the Cumming School of Medicine at the University of Calgary and Alberta Health Services are conducting a research study.

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 described here, or information 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 for your records.

You have been identified as a possible participant in this study because you had rapid racing of your heart (ventricular tachycardia (VT)) treated by your implantable defibrillator (ICD) despite a previous ablation procedure and/or medications. Your doctor has determined you may benefit from a new treatment option to suppress these dangerous heart rhythms. Your participation in this research study is voluntary

**WHY IS THIS STUDY BEING DONE?**

The purpose of this research study is to test whether a radiation technique is called *Stereotactic Arrhythmia Radioablation* (STAR) is safe and helful in patients with heart disease and ventricular tachycardia in whom conventional antiarrhythmic management has been unsuccessful.

# Ventricular Tachycardia (VT) is a dangerous abnormal heart rhythm (arrhythmia) that comes from the bottom chambers of the heart (ventricles). This rhythm is one of the most common cause of sudden death in patients with heart disease. Implantable Cardioverter Defibrillators (ICDs), Ablation procedures and Antiarrhythmic medications have been successful in bringing back and maintaining a normal heart beat for some, but others experience side effects or are not helped by these treatments alone. These patients may need further treatment to suppress these dangerous heart rhythms. Areas in the heart which may be “scarred” are often the place where VT can start. Scientists think ablation with radiation of these scarred areas will not affect heart function but could stop the arrhythmias. A few patients around the world have received this treatment and most have seen a decrease in their arrhythmias.

This radiation technique is called *Stereotactic Arrhythmia Radioablation* (STAR) when is applied to the heart. It is similar to radiation that would be used to treat brain or lung cancer tumours.

Much like catheter ablation, the STAR ablation would target regions in the heart scar capable of generating arrhythmia.

If you chose to enroll in the study then you will treated with STAR and then followed to see if it has been helpful. The STAR technology provides hope to many patients who have limited options.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

We are planning to enroll 20 patients over three years in Calgary.

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

# If you enroll in the study, tests will be done to determine the scar areas of the heart that your ventricular arrhythmias are coming from. Sometimes this might already be available from the tests you have had done in the past. These will be imaging tests such as MRI, CT, Echocardiogram, and/or nuclear medicine scans. Results of these and other investigations including blood tests, will be accessed by the study team through the Alberta NetCare System (a Province wide database containing your health records). Study staff will also take samples of your blood for a special lab in the University of Calgary.

A specific procedure to see what part of your heart is responsible for your VT (so we can focus your STAR treatment) will be done in the Electrophysiology lab prior to your STAR treatment. This procedure is called NIPS (Non-invasive pacing study). You will be lightly sedated: asleep but not unconscious, with medications into an intravenous tube in your arm. We will then program your ICD to make you have VT while we are monitoring you. There is an extremely small risk we will not be able to put your heart back into normal rhythym.

A special CT scan will also be done with intravenous dye as a reference to plan for your radiation treatment on your STAR procedure day.

You will be scheduled for radiation treatment of the scar at the Tom Baker Cancer Centre on the Foothills Hospital Site. You will not feel any sensation during the radiation treatment and usually takes about 15-20 minutes. You should not eat or drink anything from midnight the day prior to your STAR procedure. The study team will instruct you specifically regarding your medications. You may NOT drive home from the procedure or (privately) for 4 weeks following. Commercial driving will be restricted for 3 months following the procedure. Additionally, if you experience VT episodes, have and ICD (implantable cardioverter defibrillator), and/or heart failure then you may have further driving restrictions.

Your ICD will be checked to ensure no changes have occurred from the treatment that may require reprogramming. If reprogramming is needed it will performed at this time.

**WHAT WILL HAPPEN WHEN I AM FINISHED the STAR ABLATION?**

You will have a blood samples taken at your local lab within 24-36 hours of the procedure to look for effects of the radiation on your heart. If these results are abnormal, you will be asked to return for an inperson assessment. These blood tests will be taken again as described below.

You will be seen in person for a health assessment and further blood tests at 3-5 days and 6 weeks following the STAR procedure. Blood for these tests will be taken from a vein in your arm by trained study or laboratory staff. 3 tubes, or approximately 20ml (~4 teaspoons) will be taken.

* A check of your ICD will be done either in person or through remote monitoring and a phone call at 3-5 days, 6 weeks, 12 weeks,and 6 months following your STAR procedure and as needed

Imaging tests of the heart (CT, MRI, or ultrasound/Echo) may be repeated at 12 weeks and 6 months to assess for damage from the radiation to the heart and also to see if your scar has changed.

* You will be asked questions about changes in your health and to complete Quality of Life questionnaires (at yearly visits only).
* An optional “perception interview” will be done at study conclusion.

**HOW LONG WILL I BE IN THIS STUDY?**

We will collect most of our data in the first 6 months after the STAR ablation procedure but will continue to collect data from your routine ICD checks for up to 3 years.

# ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

You will receive radiation exposure in this study, from the procedure itself as well as the required CT scans.

Radiation can result in cancers, but in general, radiation from this study to result in any cancers would take 20-30 years and is estimated to be in the 1-2% lifetime risk.

 There is a risk for allergic reaction to the dye used in the CT scans. Patients who are allergic to or sensitive to medications, contrast dye, iodine, or shellfish should notify their physician.

There is possible risk associated with MRI that you may feel anxious/claustrophobic (afraid or

uncomfortable being in small spaces). If this is the case, you may ask the technologist to stop the

examination. A small number of people have minor side effects after receiving the dye. There

is a 5-10% chance you will have a headache, a 7% chance of discomfort at the injection site, and

less than a 3% chance of vomiting, dizziness, or a skin reaction. There is a very remote 0.001%

chance of some individuals having a severe allergic reaction to the contrast dye. If you do not feel

well after the injection, please inform the technologist.

It is also possible that the STAR treatment may affect other parts of the heart or other organs in the path, such as your heart or lungs, which usually shows up as as inflammation, (called myocarditis or pericarditis). You may or may not feel discomfort from this inflammation. We will be collecting a blood sample to monitor you for damage to the heart musce and you will be asked to be assessed urgently if these results are abnormal. Anti-inflammatory steroid medications may be ordered by your study doctor for a limited time period if necessary.

The NIPS procedure has a small risk (estimated 1/1000) of having a dangerous heart rhythm which we can not correct resulting in death.

There is a 1-2% risk of a connection (fistula) forming between the heart and the swallowing tube (espophogus) from the STAR procedure. This an extremely serious development and you will be asked to obsevrve for any of it’s early signs. You will be required to have an empty stomach (nothing to eat otr drink from midnight before the procedure) to decrease this risk. The doctors also use a lower radiation dose in this area.

There are no concerning reports of STAR affecting the function of your ICD. But there is only minimal experience. Your ICD will be checked immediately after treatment as well as at every follow-up visit.

You may experience some temporary discomfort when the blood samples are taken or intravenous needles are insertred in your arm. There is a small risk of bruising, or swelling at the site where the needle is inserted, and some people may feel faint and dizzy.

You may find the questionnaires you receive during the course of the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find too distressing.

REPRODUCTIVE RISKS:

The radiation from some of the imaging tests, intravenous contrast used for tests, and the radiation treatment may pose a risk to developing fetuses or to babies who are being breastfed.

**Female participants**

If you are of childbearing potential (sexually mature woman who has not undergone a hysterectomy or who has not been post-menopausal for 24 consecutive months), you must do one of the following while in active intervention stages of the study and for three months after:

* you must use a medically approved effective method of birth control; or
* you must not have sexual intercourse that could result in pregnancy.

In addition, women who are breastfeeding are not eligible to participate in this study.

**Male participants**

If you are capable of fathering a child, you must do one of the following while in active intervention stages of the study and for three months after:

* you must use a latex condom every time you have sexual intercourse with a female partner; or

## you must not have sexual intercourse that could result in pregnancy.

COVID 19 Related Risks

As the majority of vists for this study must be done in person to allow for device interrogation, blood draws and physical examinations, there is an added risk of you being exposed to COVID 19 from other peple 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 POTENTIAL BENEFITS IF I PARTICIPATE?

If you agree to participate in this study there may or may not be a direct benefit to you.You will be in the study because you have been identified as having recurrent ventricular tachycardia even after receiving standard treatments, so your condition may be improved during the study but there is no guarantee that this experimental procedure will help you. The information we get from this study may help us to provide better treatments in the future for patients similar to you.

# WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE

# You do not have to participate in the study, however there are no further standard treatments available to treat your condition. Alternative options may include more antiarrhythmic medications and/or catheter ablation if your doctors feel the benefits would outweigh the risks to you. Other options such as palliative care or medical assistance in dying may need to be considered. Rarely heart transplant might be an option.

# CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. They will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the STAR procedure can continue to be 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 would be most helpful for you.

# CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

# 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 consult with medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care.

Consent to tell you this information is at the end of this form.

**WITHDRAWAL OF STUDY DATA:**

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study because withdrawal of data in clinical trials could bias results. You may request that your data be removed for up to 30 days after an interaction with the study team.

Data cannot be withdrawn it has been published or otherwise communicated. Any published data will be de-identified so that here is no way to identify you or your involvement in the study.

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

You will not be paid for the study. Parking costs at the hospital for any study related visits will be covered by the study.

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

The researchers will do their best to make sure that your private information is kept confidential, unless required by law. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy. The research team will handle data according the Data Management Plan as outlined below:

* Only those involved in the study, such as study coordinators, nurses, and investigators will have access to your data. Once collected, your data will be stored using only an anonymous study identification number.
* Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical study records held at the University of Calgary for quality assurance purposes.
* Data collected during your time in this research study will be de-identified and will be held in a database for future use by other researchers. Any future use of this research data is required to undergo review by a Research Ethics Board.
* No individual identities will be used in any reports or publications resulting from this study.
* During this study we may collect your laboratory results, medical information, device information and other similar information resulting from study related tests as described in the sections above. Your records and information on study participation will be kept as confidential as possible.

# HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

The researchers intend to keep the research data and records for approximately **5** years as required by the University of Calgary.

Your blood samples will become the property of the University of Calgary and stored as described below.

# WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

**Use of My Specimens:**

Your blood samples will become the property of the University of Calgary. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of University of Calgary. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens. Specimens will be retained for 10 years and then destroyed.

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

It is important that you tell the researchers if you believe that you have been injured because of taking part in this study.

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by Libin Cardiovascular Institute of Alberta, the University of Calgary, Alberta Health Services or the Researchers.You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

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

**The Research Team:**

You may contact Dr Vikas Kuriachan at 403-944-3282 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 <https://clinicaltrials.gov/ct2/show/NCT04065802>. 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.

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

It is our hope we will be able to publish the findings of this research within 5 years and could be accessed publicly. You may also ask staff in the Device clinic, or the research team. Results are also available on the clinicaltrials.gov website above.

# WHAT ARE MY RIGHTS 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.

# HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

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 participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

**SIGNATURE OF STUDY PARTICIPANT**

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Name of Participant

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Signature of Participant Date

I further consent to:

* Optional interview (telephone or face to face) regarding my perceptipons of my VT and this treatment YES ❑ NO ❑
* My research data and/or specimens may be kept for use in future research to learn about, prevent or treat other health-related problems.❑ YES ❑ NO
* Researchers to share unexpected findings about my health with me: ❑ YES ❑ NO
* University of Calgary researchers may contact me in the future to ask me to take part in other research studies. ❑ YES ❑ NO

**SIGNATURE OF PERSON OBTAINING CONSENT**

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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 will be given to you to keep for your records and reference.