Comparison of (R) and (S) Propafenone for Prevention of Atrial Fibrillation Induction

Informed Consent Date: 10/23/2019

NCT02710669

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Bjorn Knollmann **Version Date: 11/6/18**
Study Title: Comparison of (R) and (S) Propafenone for Prevention of Atrial Fibrillation Induction
Institution/Hospital: Vanderbilt University

This informed consent applies to adults with atrial fibrillation undergoing ablation.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have an abnormal heart rhythm called atrial fibrillation (AF), and you and your heart doctor have decided to perform a procedure called "ablation" to treat your AF. The purpose of this study is to compare the effects of two different drugs, R-propafenone and S-propafenone, to see if they will prevent the doctors from being able to cause atrial fibrillation in your heart. These drugs are not FDA approved to treat atrial fibrillation in the way they are being used in this study. There will be 243 people taking part in this study.

2. What will happen and how long will you be in the study?

The research study procedures will be done at the same time you are having your ablation procedure. You would be having the ablation procedure even if you were not taking part in the research study. Your doctor will tell you about what will happen during the ablation procedure.

When you go in to start the preparations for your ablation procedure, you will be given one of the study drugs, either R-propafenone and S-propafenone, or you may receive only fluid without any drug. Which you are given will be decided at random, like the toss of a coin. Neither you nor the doctor performing the study will know which one you are being given, but we can find out if there is a need. After you are asleep, the study drug will be given through a tube already in your vein for your ablation procedure.

Propafenone is a drug approved by the Food and Drug Administration (FDA) and is commonly used to treat irregular heart rhythms such as AF. S-propafenone and R-propafenone are not FDA approved to treat AF in the way they are being used in this study.

We will take blood (about 4 teaspoons) to check for levels of chemicals in your blood. We will also record your heartbeat during the research study. The blood will be drawn from tubes put in the vein of your leg as part of your ablation procedure after you are asleep and the procedure has started. We will record your heartbeat during the research study.

As part of the ablation procedure, your doctor will place small electrodes in your heart. As part of the research study, we will use these electrodes to make your heart beat rapidly to see if this will cause AF. We will try to do this for about 3 ½ minutes. The AF will either stop on its own or it will stop during your ablation procedure. This commonly happens during the ablation procedure even when people are not having a research study. Your doctor will then continue with your ablation procedure.

Your samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your

samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

Having your heart beat at a fast rate may cause chest discomfort, but you will be asleep during this time. These effects also commonly happen during an ablation procedure even if you were not in the research study. The doctors will monitor your heart rhythm and can correct it if there is a need.

R-propafenone and S-propafenone can cause dizziness, lightheadedness, metallic taste, new or worsened arrhythmias, blood pressure lowering, nausea, vomiting, and changes in some blood values. These side effects are less likely with only a single dose of propafenone. As part of your procedure, you will be monitored in the hospital. The propafenone will no longer be active in your body at the time you are released to go home.

5. Risks that are not known:

Because this treatment is investigational, meaning not FDA approved, there may be risks that we do not know about at this time.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. We may learn more about how AF occurs in the heart and how to prevent it from happening.

b) The benefits you might get from being in this study. None.

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You may decide not to be in this study.

9. Payments for your time spent taking part in this study or expenses:

None.

10. Reasons why the study doctor may take you out of this study:

The doctor may take you out of this study if you ask to be taken out of the study or if the abnormal heartbeat is causing serious problems to your overall health so that your procedure has to be done right away. You may also be taken out of this study for other reasons. You will be told why if this happens.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact [redacted] or Dr. Bjorn Knollmann at [redacted]. If you cannot reach the research staff, please page [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at [redacted] or toll free at [redacted].

13. Clinical Trials Registry.

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.

14. Confidentiality:

Your study records and data will be stored in a secure database. The database will reside in a password-protected secure web site supported by Vanderbilt. Only study personnel will have access to the database. Information in the database that will identify you will only be available to study personnel.

Your biological samples will be stored with a barcode. This barcode will not include any identifying information. Only study staff will have access to these barcodes. A list will be kept by study staff that will be able to link your barcode to your identifying information. Only study staff will have access to your identifying information.
Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr Knollmann and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.\

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr Knollmann and his study team may share the results of your study and/or non-study linked bloodwork, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Knollmann in writing and let him know that you withdraw your consent. His mailing address is

Dr. Bjorn Knollmann
Division of Clinical Pharmacology
[redacted]

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

Time

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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Consent obtained by:

Date	Signature	
	Printed Name and Title	Time

Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample will not be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not request your genetic information that comes from this research.

A single blood sample will be taken at the same time blood is being taken for the main part of the study. This will not take any additional time or require additional needle sticks.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Knollmann and members of his study team will have access to your name.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Giving samples for research is your free choice and you may be in the study even if you do not want your samples used or stored for gene research.

At any time, you may ask to have your sample destroyed. You should contact Dr. Bjorn Knollmann at

Dr. Bjorn Knollmann
Division of Clinical Pharmacology
[redacted]

to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research in atrial fibrillation.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____

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You are being asked to give a blood sample for genetic research. What we learn about you from this sample will not be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not request your genetic information that comes from this research.

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One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Knollmann and members of his study team will have access to your name.

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My blood/tissue sample may be stored/shared for future gene research in atrial fibrillation.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____