Official Title: Diltiazem in the treatment of atrial fibrillation or atrial flutter with rapid ventricular rate (AFF RVR): Comparing calcium pre-treatment vs placebo in prevention of diltiazem induced hypotension

NCT05661942

Approval Date: 9/12/24

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Version date: 11/2/2022	Medical Record # _____

Subject name: _____ Subject date of birth: _____

Advocate Aurora Health
Consent to Participate in a Research Study

Study Title	Diltiazem in the treatment of atrial fibrillation or atrial flutter with rapid ventricular rate (AFF RVR): Comparing calcium pre-treatment vs placebo in prevention of diltiazem induced hypotension
Study Investigator	Michael Cirone, M.D. [redacted]

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about the use of Calcium in the management of atrial fibrillation with rapid ventricular response because you are currently in atrial fibrillation with rapid ventricular response.

This form describes the study and what you would need to do. We will answer any questions you may have so that you can make an informed decision.

What is a research study?

A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

- Does this work?
- Is it safe?
- What kind of treatment is better?
- How do people think or feel about this?

To answer these questions, doctors and scientists need volunteers to participate in research studies. These volunteers are called "subjects." The doctors and scientists who run the research study are called "investigators." Other people who help them run the study are called the "research team."

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

Sometimes a drug or device being tested makes research subjects better, and sometimes it doesn't. When you are a subject, the main purpose is to see if the study drug or device works and if it is safe There may be side effects or risks to you, including some we don't know about right now.

A research study has specific rules the investigator must follow. The study rules may say that subjects can't receive certain medications or treatments while they are in the study. We will explain the rules you will have to follow. If you can't or don't want to follow these rules, then you should not participate.

What is the purpose of this study?

In this study, we want to find out if the use of calcium in addition to a rate controlling medication that you would otherwise be receiving in the ED today will reduce the incidence of low blood pressure.

Where will this study take place?

This study will take place at Advocate Christ Medical Center. Michael Cirone, M.D. expects to enroll about 92 subjects

What is involved?

As a subject, you will be responsible for:

- telling the investigator if you are feeling bad or worse than before
- following the directions of the investigator and research team

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will review your medical history and labs to see if you qualify to be in the study.

If you meet all criteria to be in this study, you will be randomized to one of 2 groups. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 50% chance of being assigned to each group. Group 1 – receives calcium gluconate in addition to Diltiazem, Group 2 – receives normal saline in addition to Diltiazem. You cannot choose which group you will be in. We will not tell you which group you are in. The investigator and research team will not know your group, either. However, we can quickly find out which group you are in if we ever need to know for your safety.

You may receive a placebo instead of the study drug. A placebo looks like the study drug, but does not have active ingredients. Comparing a study drug to a placebo helps investigators tell how well the drug works.

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

Heart Rate and Blood Pressure will be evaluated at 5 and 15 minutes for research purposes.

The following tests and procedures are part of regular medical care. This means you will have these whether you choose to be in this study or not.

- Lab work including electrolytes
- An EKG (heart rhythm)

Your identifiable private information, collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Are there any risks to me?

There may be risks, side effects and discomforts if you choose to participate in this study. These can be physical, emotional, financial or social. The ones we know about are listed below.

There may be side effects from the study drug, Calcium gluconate. Many side effects go away, but sometimes they can be serious, long-lasting, or may never go away. There may be other side effects that we don't know about yet, so be sure to tell the investigator about any unusual symptoms.

Risks of Calcium Gluconate

Less common (between 1-10 in 100 people)
• Extravasation (leaking from the vein) – local tissue inflammation • Tingling Sensation • Hypotension (low Blood Pressure) • Bradycardia (low Heat Rate)

Are there any benefits to me?

You may or may not benefit from being in this study. Your disease or condition could improve in the following ways: your heart rate may slow down (improving palpitations or chest discomfort), your

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

blood pressure may remain stable (allowing you to receive diltiazem to be given to help slow down your heart rate).

It is also possible that your condition could stay the same or even get worse. If the study treatment is ineffective, alternative treatment will be provided. We hope the information learned will help other patients with atrial fibrillation in the future.

How much will it cost to participate?

There will be no additional costs to you as a result of this study

Will I be paid to participate?

You will not be paid to participate in this study.

How long will I be in the study?

You will be in the study while in the Emergency Department today. Your data may remain in an encrypted file until the study is completed for up to 2 years

The study may be stopped early by the investigator. You could be asked to stop being in the study for any of the following reasons:

- for your safety

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator know. There may be special procedures to follow for your safety.

Your only choices are to participate, or not to participate. Alternative treatments if you choose not to participate could include diltiazem without calcium pretreatment or other rate controlling and anti-arrhyhtmic medications at physician discretion (for example: metoprolol or amiodarone). It is up to you whether you want to be in this study.

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

Will my records be kept confidential?

Your study records will be kept as confidential as possible. You can find out more in the section "Information about Confidentiality and HIPAA Authorization."

What if I am harmed from being in the study?

There is a chance that you could be harmed during the research activities occurring as part of this research study. If you do suffer harm, make sure that the study doctor is aware. We will bill your insurance carrier, if you have any, and you will have to pay any usual co-pays or deductibles. If you have Medicare, we may send information that identifies you to Medicare. If you do not have insurance or if your insurance does not cover your treatment, we will bill you for the costs of the treatment.

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

If you want to know the results of the study once it is over, you can ask the investigator.

Who oversees this study?

The Advocate Aurora Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at Advocate Aurora Health to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research	Michael Cirone, M.D>	[redacted]
You have questions about your rights as a research subject	Advocate Aurora RSPP office	[redacted]

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135 Version date: 11/2/2022	Medical Record # _____

You have questions, problems, concerns, information, input or complaints about this research study	Michael Cirone, M.D. or Advocate Aurora RSPP office	[redacted]

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

Information about Confidentiality and HIPAA Authorization

Note: In this authorization document, "you" and "your data" refer to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

Federal law provides additional protections of your medical records and related health information. That law is the *Health Insurance Portability and Accountability Act* (HIPAA). This study's HIPAA statement is provided below. You are providing your authorization if you sign this form and the accompanying consent or permission form to participate in the study.

Who will see my protected health information?

Who may have access to my information:	*Purpose:*
Advocate Aurora Health consultants and employees, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.

By signing this form, you are authorizing access to and sharing of personally identifiable health information. This includes direct access to your medical records at Advocate Aurora Health.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself; reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?
This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the study.

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

The study principal investigator and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study;
- to review the study, and to check the safety and results of the study;
- to seek government approval of an investigational study drug, vaccine, device or product if such was involved in the trial;
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care;
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number,health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

How will my information be kept confidential?

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form you were given. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves Advocate Aurora Health we cannot control how it is used, and the law may not require outside organizations to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

If this study is designed so that you are intentionally not told what treatment or study intervention you are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

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.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed

If study information is used for scientific publications or educational purposes, all identifying information will be removed.

You will receive a signed and dated copy of this form for your records.

For Medical Record Use

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date Time (optional)

_____

Witness signature (if applicable*) Date Time (optional)

**Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

_____

Legally Authorized Representative signature (if applicable) Date

Relationship to Subject: ☐ Court Appointed Guardian ☐ Heath Care Agent

Assent of subject: ☐ Not required by IRB

☐ Required by IRB

☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

☐ Obtained

For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began .
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

_____

Name of person obtaining informed consent (print) Title Phone number

_____

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

Signature of person obtaining informed consent Date Time (optional)

Advocate Aurora IRB Stamp of Review	*Complete or apply a patient label*
AA IRB #: 22.135	
Version date: 11/2/2022	Medical Record # _____

FILE A SIGNED COPY OF THIS FORM IN THE PATIENT'S MEDICAL RECORD (if applicable).
Keep the original in the investigator's research records.
Form IC 701A v. 02.22.2021

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK.