Consent Form (includes HIPAA Authorization)
Continued Participation Consent after EFIC entrance into the ARREST Trial

Title of Research Study: Advanced REperfusion STrategies for Refractory Cardiac Arrest (The ARREST Trial)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by National Institute of Health (NIH), the University of Minnesota Medical School, Cardiology Department and the Lillehei Clinical Research Unit.

Key Information About This Research Study

The following is a short summary to help you decide whether or not you would like to continue participation in this research study. More detailed information is listed later on in this form.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant. In this consent form "you" generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Why am I being asked to take part in this research study?

We are asking you for your continued participation in this research study because you had an out-of-hospital ventricular fibrillation cardiac arrest (an irregular heart rhythm that does not pump blood). You were transferred to the hospital having ongoing mechanical CPR and were randomized (like the flip of a coin) to one of 2 standards of care practiced in the Twin Cities area. This research study is being conducted to see which of two treatments (if any) has increased survival for patients with out-of-hospital ventricular fibrillation cardiac arrest. You qualified for this emergency research study and were enrolled under a process for emergency situations called EFIC (exception from informed consent). Permission was not possible because you were unable to tell us your preference and, at that time, you were unable to provide consent. The Food and Drug Administration (FDA) provides regulations that allow such research to occur. Researchers consulted with the community to obtain feedback about doing the study, then notified the public, and then obtained approval from the Institutional Review Board (IRB) prior to beginning the study.

Now, you are being asked to continue to take part in this research study. Continuing to participate in the study is voluntary, which means you can choose whether or not you want to continue. Before you make your decision, you will need to: know what the study is about, the risks and possible benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study and this consent form. This form gives you important information about the study. Please take time to review this information carefully. You may find some of the medical words hard to understand. Please talk to the study doctor or research team about this form and ask them any questions you have. You may also decide to discuss it with your family, friends, or family doctor. If you decide to continue your participation in the study, you will be asked to sign this form.

What should I know about a research study?

- Someone will explain this research study to you.

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Patients that have an out-of-hospital cardiac arrest due to ventricular fibrillation (an irregular heart rhythm that does not pump blood) and don't respond to initial treatment by paramedics, do not often survive. This study will evaluate two treatment options for out-of-hospital ventricular fibrillation cardiac arrest patients are treated once they are brought to the hospital:

Investigational Treatment option 1 (standard of care at the University of Minnesota Medical Center where this study is taking place): Patients go to the cardiac catheterization laboratory (CCL) right away whether the heart has started beating (providing pulses) or not. In the CCL, extracorporeal membrane oxygenation (ECMO) is placed on the patient which circulates and oxygenates the blood for the patient in place of their heart and lungs if needed to support their life if they become unstable or they rearrest. This allows the doctor to then look for blockages in the heart's arteries and open them up if needed.

Treatment option 2: Following arrival in the Emergency Department (ED), patients get continued treatment to start the heart for at least another 15 minutes. As soon as the heart starts beating again or if the patient arrives in the ED with a pulse, the treating physician sends the patient to the CCL to evaluate for the cause of the arrest and do an angiogram and possibly open blockages if present. In this group patients may still get ECMO placed if clinically indicated based on the judgment of the treating interventional cardiologist. Reasons to place a patient on ECMO in this case may include among others persistent low blood pressure on medicines, inability to oxygenate despite maximum ventilator support and rearrest with absence of pulses after arrival to the CCL. If the treating emergency department physician is unable to get pulses back after 15 minutes from arrival to the ED, the MD will proceed with further ACLS efforts or stop and pronounce death based on common clinical practice.

It is not clear which standard treatment (if any) is better and results in higher survival; that is the purpose for this research trial.

How long will the research last?

We expect that you will be in this research study for up to 6 months after discharge from the hospital.

The study team will contact you by phone or at your visit with your cardiologist at 3 and 6 months after discharge.

What will I need to do to participate?

You will be asked to participate in a phone call or a visit in person with the research team at 3 and 6 months to answer some questions on how you are doing. This will take approximately 15-30 min. During your hospitalization the research team will be following you and collecting data that is required by the protocol from your medical chart.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

You have suffered a cardiac arrest. There are multiple risks associated with your cardiac arrest, chest compressions, and ECMO placement. Some of these risks are stroke, heart attack, multi-organ failure and death. All patients that suffer prolonged cardiac arrest and resuscitation are at risk of surviving with poor brain function although this risk is small.

Only patients with cardiac arrest are exposed to the associated risks of CPR and ECMO-facilitated resuscitation which, if left untreated, will lead to death. Such risks are reasonable when compared to the alternative.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

The potential benefit of the research to the enrolled subjects is a possibly improved chance of survival, but this is not guaranteed.

More detailed information about the benefits of this study can be found under ***"Will being in this study help me in any way? (Detailed Benefits)"***

What happens if I do not want to continue to be in this research?

There are no known alternatives, other than deciding not to participate in this research study. Your care will continue as standard clinical care but no further data will be collected from your record.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

There will be 180 people enrolled in this study.

What happens if I say "*Yes, I want to continue to be in the research*"?

If you chose to continue to be in this research study the research team will collect data from your medical records during your hospitalization that are required per the protocol, assess your neurological status (brain function), and review of your medical bills from your hospital admission. At 3 and 6 months after discharge, the research team will ask questions to review your neurological status along with any hospital admissions or procedures that may have happened since your hospital discharge. These visits will either happen over the phone or at your regularly scheduled follow-up visit.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for having a visit or phone call at 3 and 6 months.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. You will continue to get the standard medical care offered to all our patients.

Choosing to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice to discontinue participation in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Out-of-hospital cardiac arrest that does not respond to initial paramedic treatment has a very low survival rate. Prolonged CPR occurs in all patients and leads to multiple injuries that cannot be avoided. There are other risks caused by no blood flow to the body.

Risks associated with chest compressions include injuries such as: pneumothorax (collapsed lung), hemopericardium (blood in the sac around the heart), rib fractures, solid organ injuries (blunt damage to internal organs, usually the liver and spleen), and emergency surgery to repair the damage.

Standardized mechanical CPR will be employed, in addition to manual CPR when needed, as the usual practice for all out-of-hospital cardiac arrest victims transported to the hospital with CPR via ambulance

(entered in the study or not).

Risks associated with going to the CCL include: bleeding, stroke, heart attack, lack of blood flow to the leg, and death.

Risks associated with ECMO include: bleeding due to blood thinners to prevent clotting, risk of infection from the insertion of the ECMO tubes into a vein or artery, potential need for blood transfusions, brain or nervous system damage, survival with poor brain function, renal (kidney) damage, liver damage, lack of blood flow to a limb, and malfunction or failure of ECMO equipment.

These risks are unavoidable in order to save your life. If the ECMO machine is used, it is pumping oxygenated blood throughout your body to try to give it time to rest and heal. Without this you would have died. You will be on the ECMO machine for an average of 3-5 days. During this time the risks listed above will continue, along with risk of infection, lung complications, bleeding, stroke, multi-organ failure, lack of blood flow to a limb and potential amputation, malnutrition, ECMO malfunction or equipment failure and death. Regardless of the treatment, surviving this event is a prolonged and complicated process, which, on average, takes 3 weeks before the patient can be discharged from the hospital.

As with any study that deals with Personal Health Information (PHI) there are potential risks related to confidentiality of study data and privacy. Adhering to the Lillehei Clinical Research Unit's standard, rigorous protective procedures will help maintain privacy and confidentiality.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any additional costs to you. You have and will receive standard care for your illness and it will be charged to your insurance company.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay

Will being in this study help me in any way? (Detailed Benefits)

The potential benefit of the research is a possibly improved chance of survival, but this is not guaranteed. We cannot promise any benefits to you or others for taking part in this research. However this study will help determine the best care to provide future patients.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical

records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);
- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
- The National Institute of Health (NIH)
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study.

You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

You will not be compensated for your participation in this study.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Witness:

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process

Signature Block for Adult Unable to Consent:

Your signature documents your permission for the named participant to take part in this research.

_____

Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____ _____
Printed Name of Legally Authorized Representative Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Printed Name of Person Obtaining Consent Date