utmb Health

The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: Effectiveness of Remote Ischemic Preconditioning for prevention of Contrast Induced Acute Kidney Injury in patients undergoing coronary angiograms (RIP-CI-AKI study).

IRB Number: 21-0280

Sponsor: **Nephrology & Cardiology division of Internal Medicine Department, UTMB.**

Principal Investigator: Dr. Salman Salehin.
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Why am I being asked to take part in this research study?
You are being asked to take part in this study because you are at moderate to high risk of kidney injury associated with your procedure. We want to reduce your risk through use of a procedure termed remote ischemic preconditioning (RIPC). You have been identified as someone who may benefit from this procedure.

Study Summary:
Many people who have contrast suffer kidney injury that may be serious. People who have this kind of kidney damage have increased risk of being admitted to hospital, needing dialysis or in rare cases death. This study involves reducing the risk of kidney injury that may be caused by the use of contrast with your procedure. You will be randomly selected to be part of one of two groups – group A and B. Group A will have a procedure called remote ischemic preconditioning (RIPC). RIPC will involve a blood pressure cuff being inflated on your upper arm for 5 minutes, then released for 5 minutes. This will be repeated 4 times. Group B will have a similar procedure but with less pressure. Both groups will receive fluids to make sure their kidneys are hydrated. This will be done within 2 hours of your procedure. You will then have your procedure. Afterwards, we will monitor your blood work for 2-3 days and then follow-up with you within the next 1-2 weeks. The major risk of participation in this study is discomfort/pain in your upper arm and transient nerve irritation. The major benefit is to prevent damage to your kidney and the need for dialysis.

The following things you should know about this research study:

- The purpose of the study is to reduce the risk of kidney damage in patients receiving contrast. If you choose to participate, you will be asked to have a blood pressure cuff inflated for 5 minutes and then deflated for 5 minutes. This will be repeated 4 times and will take approximately 40 minutes.
- Risks or discomforts from this research include pain/discomfort in the upper arm.
- The study will protect your kidney from the potential damage caused by contrast.
- Taking part in this research study is voluntary. You do not have to participate and you can stop at any time.

Please take your time to read this entire form and ask questions before deciding if you want to take part in this research project.

DETAILED RESEARCH CONSENT

What is the purpose of this research study?
The purpose of the study is to investigate whether remote ischemic preconditioning (RIPC) can protect people at risk of kidney damage from contrast.

How many people will take part in this study?
About 400 people will take part in this study at UTMB.

What procedures are involved as part of this research study?
If you agree to take part, you will be asked to sign this consent form and complete the following intervention, namely RIPC. This will involve applying pressure to your upper arm (with a blood pressure cuff) for 5 minutes and then releasing for 5 minutes. This will be repeated 4 times within the 2 hours before your procedure. Thus the entire RIPC protocol will take a total of 40 minutes.

In addition, you will receive the standard of care, which is provided to all patients with baseline chronic kidney disease prior to undergoing coronary angiogram. This will involve giving you intravenous fluids- 0.9% sodium chloride solution (normal saline)- in the 6-12 hours before angiogram. Volume of fluid administered will depend on your body weight. You will then go for your procedure. After the procedure, you will be given more intravenous fluids, for up to 12 hours post-procedure. We will then follow your bloodwork to see if you have had any kidney injury.

What are the possible risks for choosing to participate in this research study?
The major risks associated with the study include:

- Discomfort/Pain in your upper arm.
- Transient nerve irritation.

The above risks are limited to RIPC. They do not include risks of angiography which are separate and will be discussed with you by the primary team. Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What are the potential benefits for participating in this research study?
Your direct benefit from participation in this research project is protection of your kidney from damage associated with your procedure. You may be less likely to need dialysis or need to be admitted to hospital.

Will I be reimbursed for participating in this research study?
There will be no reimbursement for participation in this study.

Is there an alternative treatment/procedure?
The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your procedure is cancelled.
- You are unable to keep appointments or to follow the researcher's instructions.
- The researchers believe that participation in the research is no longer safe for you.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.
Data collected in this research may be used for future research or distributed to another investigator for future research without your consent.

How will my privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Who can I contact with questions about this research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Dr. Salman

Salehin at +12818189321 or, if after normal office hours, at +12818189844 or Dr. Olusola Sogbein at +14093924700.

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office at the following email: irb@utmb.edu.

Do I have to participate?
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

Signature of Person Obtaining Consent	Date and Time of Consent Obtained

Printed Name of Person Obtaining Consent