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Remote Ischemic Conditioning (RIC) to Decrease Postoperative Complications After Major Abdominal Surgery - A Phase IIa Trial

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I. STUDY TITLE: Remote Ischemic Conditioning (RIC) to Decrease Postoperative Complications After Major Abdominal Surgery - A Phase IIa Trial
Principal Investigator: Baburao Koneru, MD, MPH

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Dr. Baburao Koneru, MD, MPH is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Dr. Koneru may be reached at (973) 972-9599; His office address is Room G-595, 185 South Orange Avenue, Newark, NJ 07101

The study doctor, Dr. Koneru, or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Who might benefit financially from this research?

Research studies like this one are designed to determine whether a particular treatment is safe and effective. In certain research studies conducted at Rutgers University, a party or parties (Rutgers University, the investigatory or a drug company) may gain financial benefits.

However, in this particular research study, there are no financial benefits to anyone.

Why is this study being done?

Several complications may happen after an operation in the abdomen (or a "stomach operation"). Such complications include bleeding and infection inside the abdomen. Sometimes "leaks" may occur from stiches breaking open after operations on one's intestines. Some patients may develop breathing problems, heart attacks, strokes and kidney problems after a stomach operation. The complications are more in patients that have diabetes, high blood pressure, heart and kidney problems before the operation.
An operation produces stress on the body. This stress causes "inflammation" not only in the operation area but also in the whole body. This natural response helps protect our body. But quite often this inflammation is excessive and is harmful. In addition, the stress of the operation

puts extra burden on our heart, kidney and lungs. In some, especially those with prior medical problems, this extra stress may cause heart attacks and strokes, etc.
The study doctors are doing research with a simple treatment called ISCHEMIC CONDITIONING. This is not a medicine. In ISCHEMIC CONDITIONING, rubber cuffs (similar to those used to check blood pressure) are put on either the arm or the thigh. They are filled with air for 5 minutes and then air is let out for another five minutes. This is repeated three times.
Some doctors have found that patients getting ISCHEMIC CONDITIONING do better after heart operations. Their organs work better. This study's doctors want to make sure ISCHEMIC CONDITIONING is safe in patients having stomach operations. Also, they want to make sure that ISCHEMIC CONDITIONING does not cause too much pain. Finally, doctors want to see if it decreases inflammation, and makes your organs work better after surgery.

Why have you been asked to take part in this study?
You are about to have a stomach operation. Therefore, we are asking if you would agree to take part in this study.

Who may take part in this study? And who may not?
You **ARE** eligible to participate in this study if:

You are about to have abdominal surgery
You are 18 years of age or older
You sign a research consent form
You may have diabetes, but take only insulin or metformin for sugar control
You do not have any serious circulation problems in your legs

You **ARE NOT** eligible to participate in this study if you

Have amputations in one or both legs
Have diabetes and take certain tablets for sugar control
Have circulation and nerve problems in your legs
Take nitrate pills for heart or other medical problems
Are extremely overweight
Are pregnant

How long will the study take and how many subjects will participate?
You will take part in this study from the time you sign this consent form to 30 days after your operation. Once you are discharged, no extra trips to the hospital are needed for the research. Approximately one hundred patients like you will participate in this study.

What will you be asked to do if you take part in this research study?
Nothing will be done until you go to "sleep" (anesthesia) for your operation. You will receive a total of 3 ISCHEMIC CONDITIONINGs before you leave the hospital. The first one will be before your operation starts. The second and third ISCHEMIC CONDITIONINGs will be on the first and second day after your operation. If you are discharged from the hospital the day after the operation, you will receive ISCHEMIC CONDITIONING only once after the operation.

Each ISCHEMIC CONDITIONING treatment is as follows. A standard sized rubber cuff will be placed on your thigh. The rubber cuff will be pumped with air for 5 minutes. Then the air will

be let out and left for 5 minutes. This will be repeated for a total of 3 times. This constitutes one CONDITIONING treatment.

In addition, the study doctors will take 10 mL (approximately two teaspoons) of blood from you 4 times during this study. The first and the second blood samples will be taken before you wake up from anesthesia. Hence you will not feel any discomfort or pain from that. It is very likely that you will be awake when the third and fourth blood samples are taken. If you have an "IV" already in place, the blood samples will be taken from them. If there are no IV lines or they don't work, we may need to "stick" you to take blood. If so, you will experience some discomfort from that. A few drops of blood may ooze or you may get a bruise at the puncture site. Very rarely (1 in 2,000), a slight infection may occur at the puncture.

Blood samples will be collected only by study doctors and staff. Blood samples for this study will be analyzed by study doctors. Your insurance will not be billed for collection or analysis of blood samples. Any leftover blood samples will be stored for possible future study.

What are the risks and/or discomforts you might experience if you take part in this study?
When study doctors do the first ISCHEMIC CONDITIONING, you will not know and feel anything.

During the second and third ISCHEMIC CONDITIONINGS, you are likely to have recovered from anesthesia. You may be under sedation and/or receiving pain medication injections. If you are awake, you may feel some discomfort or slight pain in the leg for a minute or two when the rubber cuff is pumped with air. Also, you will experience some tingling and "pins and needles" for a minute or two when the air is let out. The goal of this study is to make sure this pain is not excessive and that CONDITIONING does not interfere with the care you otherwise receive.

If you have significant pain from the conditioning, you have the right to opt out of receiving further conditioning. If you do so, the study doctors will still use information about you. You may also withdraw your consent for the use of your data, but you must do this in writing to Baburao Koneru, M.D, MPH, MSB G-599, 185 South Orange Avenue, Newark NJ 07101.

Are there any benefits for you if you choose to take part in this research study?
You may have fewer complications from abdominal surgery. If conditioning makes your organs work better, you may be discharged sooner from the hospital.

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?
The alternative is to proceed with your operation without participating in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?
Your participation in this study will be free of cost to you. You or your insurance carrier will be billed for your routine care.

Will you be paid to take part in this study?
You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Information collected about you will be in paper records and in a computer dedicated to research use. The paper records will be stored in locked file cabinets in locked rooms. Access to computers containing information about you will be restricted by passwords. Also, those computers will be stored in locked rooms. Only people connected directly with the study will see or receive information about you.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. 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.

What will happen if you are injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include the risks associated with having a stomach operation. Your regular doctors and nurses have already provided you with that information in your meetings with them.

In addition, it is possible that during the course of this study, new adverse effects of ISCHEMIC CONDITIONING that result in physical injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. Your health insurance carrier or other third-party payer will be billed for the cost of this treatment provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. The University will provide no financial compensation. No other type of assistance is available from the University.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time during the study.

If you do not want to enter the study or decide to stop participating, your relationship with the surgical team will not change. You may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Baburao Koneru, M.D, MPH, MSB G-599, 185 South Orange Avenue, Newark NJ 07101. At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Baburao Koneru, MD, MPH
Department of Surgery
973-972-9599

If you have any questions about your rights as a research subject, you can call:

IRB Director, Newark
(973)-972-3608

And

Human Subjects Protection Program, Newark
(973) 972-1149

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY
Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?
You are being invited to take part in this research study. This is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help the study doctors complete this research.

What information about me will be used?

All information in your medical record except for dental records and financial and billing information.

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards;
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services.

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study).

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to Baburao Koneru, MD, MPH, Room G-595, 185 South Orange Avenue, Newark, NJ 07101, and tell him of your decision.

How long will my permission last?
Your permission for the use and sharing of your health information will last until the end of the research study.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name (print): _____

Subject Signature: _____ Date: _____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name): _____

Signature: _____ Date: _____

3. Signature of Consent Process Witness:

I have observed the consent process, which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not the subject, his/her guardian or authorized representative, or a researcher on this study and can attest that the requirements for informed consent to the medical research have been satisfied.

_____	_____	_____
Signature of Witness	Printed Name of Witness	Date