Title:Pre-surgical arm exercises prior to creation of a forearm AV fistula in hemodialysis patients with end stage kidney disease. A pilot study
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Pre-surgical arm exercises prior to creation of a forearm AV fistula in hemodialysis patients with end stage kidney disease. A pilot study

Study doctor: **Michael V. Rocco, MD**

Institution name: **Wake Forest School of Medicine,**
Department of Medicine
Section on Nephrology

Site address: **Wake Forest School of Medicine**
[redacted]

Phone number: [redacted]

Introduction

You are being asked to take part in a clinical trial. A clinical trial is a type of research study. To keep the information in this form simple we shall refer to a clinical trial as a "study". The study staff will explain the study to you. You will be informed of the purpose of the study, what is required of you, and any potential risks or benefits of taking part.

The study will only include people who choose to take part. You should ask the study staff any questions you may have about the study.

This consent form has been reviewed and approved by the Wake Forest Independent Review Board (IRB). This board reviews research studies to protect the rights and well-being of the people taking part. Some of the information in this consent form is required by law.

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What is "giving your consent"?

Only you can decide if you want to take part in this study. You should only make your decision after reading all the questions and answers in this form.

You may talk to your family, friends and/or your family doctor to help you make your decision. You can take as much time as you like to decide.

After you have read the entire form, you will be given the chance to ask any questions that you may have. When you have had the chance to ask any questions and they have been answered to your satisfaction, if you decide to take part, sign the pages at the end of this form to show that you agree to be part of the study. This is called "giving your consent".

Even after you have signed this consent form you can change your mind and decide not to participate in the study. You do not have to give a reason, and you will continue to receive care as normal.

How does the study work?

Your kidney doctor has recommended that you have a fistula placed so that you can receive hemodialysis treatments in the future. An arteriovenous fistula is created by surgically connecting an artery in the arm with a vein in the arm. This procedure is needed in order to allow the vein to grow big enough so that it can be used to place the dialysis needles needed for your hemodialysis treatments

This study will assess the effect of exercise performed prior to placement of an arteriovenous fistula on the maturation of the arteriovenous fistula for dialysis. Approximately 60 subjects will participate in this study. One group of up to 30 people will be given an exercise intervention while the other group of up to 30 people will not be given the exercise intervention. Each subject will be randomly assigned (similar to a coin flip) into one of the two groups. There is an equal (50-50) chance of being placed in either group. Neither you nor the study doctor can choose which group that you are in.

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Why is this research study being done?

An arteriovenous fistula is the preferred method of gaining blood access for chronic hemodialysis access. Up to 40% of patients who have an arteriovenous fistula placed are not able to use that fistula for dialysis due to the failure of the fistula to mature so that the veins get large enough to be used to place the needles needed for hemodialysis.

Although it is common to perform exercise on a daily basis *after* an arteriovenous fistula is placed, it is not known if this exercise program can increase the chance that the fistula can be used for dialysis. In this study, we would like to determine if performing exercise for at least 6 weeks *prior to* creation of the AV fistula will increase the chance that a fistula can be used for dialysis.

What am I expected to do in this study? How will being part of this study affect my lifestyle? How long will I be in the study?

You can expect to be in this study for about 8 weeks. If you are in the exercise group, you will be asked to perform hand grip exercises on a daily basis. If you are in the control arm, you will not be asked to perform exercise or to undergo any other procedures for the study. In both arms of the study, we will ask your kidney doctor and dialysis unit for information about the use of your fistula for dialysis after fistula placement. We will also ask to obtain the results of any studies that your doctors ask to be done to either assess your arm for fistula placement or to evaluate your fistula after it is created. Your enrolment in the study will not affect any of the tests or procedures that are normally done to create an arteriovenous fistula.

If you are selected for the exercise group, you will be asked to use a hand grip on a daily basis, similar to the hand grip shown in the picture below:

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The schedule for the use of the hand grip on a daily basis is shown below. Note that the schedule shows that the number of hand grip squeezes to be performed each week increases until week 5 is reached, after which time the number of squeezes will remain constant until the time of fistula placement. Note that the exercise each day can be divided up into 2 to 4 sessions per day:

Week 1: 400 squeezes / day
Week 2: 500 squeezes / day
Week 3: 600 squeezes / day
Week 4: 700 squeezes / day
Week 5 and subsequent weeks: 800 squeezes / day

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Assuming 20 squeezes per minutes, the exercise time each day would be as follows:

Week 1: 20 minutes

Week 2: 25 minutes

Week 3: 30 minutes

Week 4: 35 minutes

Week 5 and subsequent weeks: 40 minutes

Note that we will review your medical record to obtain information about your medical history, your recent vital signs (blood pressure, pulse, height and weight) and your current medications as well as any imaging studies that are performed on your arm as part of your routine care.

What side effects can I expect from this study?

The only potential side effect from this study is from the use of the hand grip device.

These side effects include:

- Discomfort, soreness, or pain during or after the hand grip session.
- Fatigue during or after the hand grip session.
- Aggravation or development of tendonitis, or tendonitis-like symptoms.
- Aggravation or development of repetitive motion injury.
- Aggravation or development of arthritis, or arthritis-like symptoms.
- Tingling, numbness, or a twitching feeling during or after the hand grip session

What benefits can I expect from this study?

Taking part in this study may or may not make it more likely that your fistula will be usable for your chronic hemodialysis sessions. You may not have direct benefit from participating in this study.

Knowledge from this study may help doctors better understand how to improve the chances that a fistula will be able to be used for dialysis. It may also help future

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patients.

You will have an opportunity to learn of the results from this study. You may ask your study doctor for the results and to have them explained to you.

Are there alternatives to taking part in this study?

You may choose not to take part in this study. This will not affect the treatment you are currently receiving for placement of your fistula for dialysis.

Will I receive payment to be part of this study?

You will not receive any compensation for this study.

Will I have to pay anything to be part of this study?

You do not have to pay anything to be a part of this study. If you assigned to the exercise arm, you will be given a hand grip to use. You will be asked to return the hand grip to the study coordinator at the time that your fistula is created.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

What About My Health Information?

In this research study, any *new information we collect from you* and/or *information we get from your medical records or other facilities* about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

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- Your name, address, telephone number, health insurance number,
- Your age, gender, ethnic and racial background,
- Information about your life style, health, medical condition and medical history,
- Information about your study treatments and response to study treatments,
- The data resulting from analyzing the biological samples collected.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.
We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

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Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Michael Rocco, MD, that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

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Michael Rocco, MD

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.
By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

Do I have to stay in the study?

- No. You can leave the study at any time without penalty or loss of benefit. Tell the study doctor if you no longer want to take part. Your choice will not change the quality of care you receive outside of this study.

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- If you choose to stop taking part in the study, although you do not have to give a reason, it will be helpful to know why you decided to stop.

Can I be asked to leave the study?

Yes. You may need to leave the study if:

- You do not follow study instructions.
- The study doctor thinks it is best for you to stop, for example if you have specific health problems.
- You get new health problems during the study that might not work well with the study set-up.

Sometimes the entire study needs to be stopped for everyone. If this happens, the study doctor will explain the reason to you as soon as possible.

What happens if I decide to leave the study?

- If you do not wish to continue with the study, the study personnel will still obtain information about the use of your fistula from your kidney doctor and your dialysis unit after your fistula is created. .
- If you withdraw your consent to all follow-up, no further study-related contacts or information collection will occur, and the study doctor will no longer use your health information, or share it with others.
- Any information that is available to the public and is relevant to the study, including your health and well-being, may be used, where allowed by local law, even if you withdraw consent to all follow-up in the trial.
- All the data and samples collected before you left the study will still be used for the study. You may ask that your samples be destroyed but any data already collected about your samples will be used for the study.

<u>Whom should I call if I have questions or problems?</u>

For questions about the study or in the event of a research-related injury, contact the study investigator, Michael Rocco, MD at [redacted] (24 hour number).

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The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted] .

You will be given a copy of this signed consent form.

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CONSENT for Clinical Research Study:

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By signing below, I show that:

- I have read this form. The study has been explained to me in a language I understand.
- I have discussed the study with the study doctor or study nurse and have asked questions. I am satisfied with the answers.
- I have had enough time to make my decision.
- I freely agree to take part in the study described in this form.
- I have been given names of study staff who I can call if I have any questions about the study.
- I agree that the study staff, and others may have access to my medical and personal information for use as described in this form.
- I know I can leave the study at any time without giving a reason.
- I know that the study doctor can ask me to stop taking part in the study at any time and he/she will tell me the reasons why.
- I know that I cannot be in another study while I am taking part in this study.
- I agree that my information may be shared with people who are not healthcare providers and that the information would no longer be protected by US federal privacy rules (such as “HIPAA”).
- I agree that the study doctor may tell my doctor that I am taking part in a study.
- It has been explained to me that I have not waived my legal rights by signing this document. I will receive a signed and dated copy of this signed document to take with me.

Signature Date Time

Printed name

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A researcher or the study staff member going over the informed consent must also sign and date each consent.

By signing below, I show that:

- I have given this form and explained the study to the subject.
- I have given the subject the chance to ask questions and I have answered them to his/her satisfaction.
- I have given the subject enough time to think and decide whether or not he/she wants to participate in the study. I explained that he/she may talk with others before making a decision.
- A copy of this Informed Consent Form has been provided to the subject.

Signature of study staff conducting consent Date Time

Printed name of study staff

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