Biologic Mechanisms of Early Exercise After Intracerebral Hemorrhage

NCT04027049

10/4/2019

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Biologic Mechanisms of Early Exercise after Intracerebral Hemorrhage and Acute Ischemic Stroke: A PilotRandomized Trial of Cycle Ergometry

Application No.:

Principal Investigator: Elizabeth Zink, MS, RN
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Baltimore, Maryland 21287
410-502-5726

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

This research is being done to determine whether the addition of cycling in bed will affect the inflammation process in the brain and body after a stroke. Participants in the study will be randomized into one of two groups: One group will have two cycling sessions per day where they are placed into an in-bed cycle for 20 minutes each time. The second group will not be placed on in-bed cycle and instead will continue to receive all usual medical and nursing care. A specially designed "in-bed cycle", which moves the legs just like they were on a bicycle while they are lying in bed will be used for the in-bed cycling group. The second group will carry out the usual activities such as having their arms and legs exercised, moving in the bed or getting out of bed to a chair as they are able to participate. These two groups will be compared to determine if the in-bed cycling makes a difference in the inflammation that commonly occurs after brain stroke. Both groups will continue to receive normal medical care.

How many people will be in this study?
This study will include up to 100 people from Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- Fill out questionnaires about your physical activity and health before you came into the hospital.
- You will be randomly assigned by a computer program to receive the cycling treatment plus all routine care. You will still be evaluated and treated by rehabilitation therapists and mobilized by the nursing staff regardless of what group you are randomly assigned to.
- Allow your legs to be moved in the cycle and participate in moving your legs yourself if you can. These activities will be added to any sessions you may have with other staff such as nurses, physical therapists, occupational therapists or speech language pathologists.
- If you are assigned to the cycling activity you will be asked if you are having pain or discomfort and can stop at any time.
- You will be asked by a study team member to move your arms and legs against resistance to test your strength 1 time per day for the 7 days that you are participating in the study. This is part of normal medical care for your condition. You will also be asked to participate in testing your strength on the day that you are discharged and 30 days after the beginning of your illness even if you are not in the hospital.
- A study team member will be watching your heart, blood pressure, pressure in the brain if you have this type of monitor in your head and number of times that you are breathing each minute.
- You will be asked to give a teaspoon of your saliva to be tested for substances that measure inflammation in your body at three times during the 7 day study period.
- A study team member will collect two teaspoons of blood from a tube that is already in your artery as a part of the medical care that you are receiving or by using a needle to collect the blood from your vein 1 time on three different days during the 7 day study period. We will try to remove this sample at the same time as other samples are being withdrawn for your care.
- A study team member will collect 1 teaspoon of spinal fluid form your cerebrospinal fluid drain, if you have one, 1 time on three different days during the 7 day study period. We will try to remove this sample at the same time as other samples are being withdrawn for your care.
- You will be asked a series of questions about your ability to perform different tasks like getting dressed, eating and going to the bathroom in a survey that will be given to you on the day that you are transferred from the ICU and approximately 30 days after the beginning of your illness that brought you to the hospital. The study team will schedule a visit with you when you have other appointments at Johns Hopkins facilities.

Request to collect and store biospecimens for future research

As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research. This research could include other diseases.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*.

Will you allow us to store the biospecimens we collect for this study for use in future research?

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

How long will you be in the study?

- You will be in this study for up to 2 months. During the first 7 days of the study you will have blood, saliva and spinal fluid collected if you have a drain that allows us collect the spinal fluid as a regular part of your care. If you are assigned to the cycling group you will participate in 20 minutes f cycling 2 times per day for 7 days.
- You will be visited by a member of the study team on the day that you are discharged so that they can test your strength and give you a questionnaire about your physical functioning.
- You will be visited by a member of the study team 30 days after the beginning of your illness so that they can test your strength and give you a questionnaire about your physical functioning. The study team will schedule a visit with you when you have other appointments at Johns Hopkins facilities. If we are not able to reach you right away we will keep trying to contact you for a month. After 60 days from the day your illness started we will stop trying to contact you about this study.

4. What are the risks or discomforts of the study?

Cycling
- Muscle soreness
- Small increase in heart rate and blood pressure

Blood sampling
- Pain and/or a bruise at the blood draw site unless blood is able to be drawn from an existing catheter in the artery

Saliva sampling
- No risks

Spinal fluid sampling
- Infection is less likely, however is possible if your catheter has to be accessed more than usual to obtain samples for the study

If you are assigned to the treatment group, you may get more tired after the cycling sessions.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?

If you decide not to join this study, you will still be evaluated and treated by rehabilitation therapists if your doctor or nurse practitioner orders this and nurses will mobilize you as you are able. You do not have to join this study to get treatment.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. How will your 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 (which may include

information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins 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.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

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 and in our Notice of Privacy Practices; however, people outside Johns Hopkins 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 fax 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.

12. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors

- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Ms. Elizabeth Zink at 410-502-5726.. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Ms. Elizabeth Zink at 410-502-5726 or Dr. Wendy Ziai at 410-955-7481 during regular office hours.

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

For ADULTS NOT CAPABLE of GIVING CONSENT (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)*

_____

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law) Date/Time

_____

Signature of Witness to Consent Procedures (Print Name) Date/Time
(optional unless IRB or Sponsor required)