Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAS2529
Principal Investigator: Victoria Leavitt (vl2337)
IRB Protocol Title: Aspirin for Exercise in Multiple Sclerosis (ASPIRE)

General Information

Consent Number: CF-AABX0500
Participation Duration:
Anticipated Number of Subjects: 60
Research Purpose: The purpose of this study is to investigate the relationship between body temperature, fatigue and multiple sclerosis.
This study examines the effect of aspirin and acetaminophen on body temperature in people with MS, and the effect it may have on exercising.

Information on Research

You are being asked to join a research study funded by the National Institute of Health (NIH) because you have a diagnosis of Relapsing Remitting MS and have reported heat sensitivity. This consent form explains the research study and your part in the study. Please read it carefully and take as much time as you need.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. This trial is identified by its clinical trial number: NCT03824938.

Please ask questions at any time about anything you do not understand.

Study Procedures: If you consent to participate, you will undergo the following during the study visit:

Screening for the study will include a brief depression screener. You will complete 3 study visits, separated by at least 1 week. Study visit sessions will be scheduled between 9 am - 5 pm at the same time of day (+/- 1 hour). At each of the three study visits, the following study procedures will be repeated the exact same way.

You must first refrain from eating for two hours prior to the scheduled session. You will be randomized (similar to flipping a coin, you will have an equal, random chance of being assigned to any of the three groups) to receive either aspirin (standard dose, 650mg, provided in the form of one capsule), acetaminophen (standard dose, 650mg provided, in the form of one capsule), or a placebo (one capsule with no therapeutic effect). After having your ear temperature taken and completing brief questionnaires about your current level of pain, mood, and fatigue, you will complete a grip strength test with a study coordinator using a Dynanometer. You will then be given a pill to take. Neither you nor the investigators will know which pill you have been given until after the study is completed. You will receive a different study treatment at each visit, ensuring that you will take all three study drugs over the course of the three separate study visits. After being administered the pill, you will relax for one hour (the estimated time for aspirin and acetaminophen to reach the highest concentration in the bloodstream), before once again having ear temperature taken and completing the grip strength test again.

During the waiting period after taking the study drug, the study team will collect data and administer questionnaires. Study personnel will familiarize you with a scale that will be used during your exercise session to measure how tired you are feeling (your level of exertion). Once that has been completed, an exercise physiologist will give you an exercise test on a stationary cycle. You will wear a face mask so that we can measure your respiration during exercise. We will also continuously monitor your heart rate with EKG monitoring that will have 12-leads attached to your body, as is the same with any clinical EKG. Your blood pressure, ear temperature and feelings of exertion will be recorded every 60 seconds during exercise. The exercise test will begin with a 3-minute warm up phase and then a progressed ramped increase, which will involve cycling until you feel too tired to continue. For most people, this is not longer than about 8-12 minutes. After you finish, blood pressure, ear temperature, and exertion will be recorded again, and we will have you fill out some questionnaires on your current level of pain, mood and fatigue, as well as complete the grip strength test with the Dynanometer one last time. At the end of each session, we will ask you whether you think you were given aspirin, acetaminophen, or a placebo.

Future Use of Data

We will use your data for the research described in this form and for other future research. We will label your data with a code instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a password protected computer and locked file.

Identifiers will be removed from all identifiable private information and, after such removal, the information could be used for future research studies without additional consent from you.

Any clinically relevant research results will be disclosed to you upon completion of the study.

Risks

Exercise causes exertion. To ensure your safety if you participate in the exercise condition, we will consult with your physician before enrolling you to make sure you meet all study criteria. The one-on-one exercise sessions you take part in will be overseen by a certified exercise physiologist with experience working with patients who have a variety of medical conditions. In addition to the exercise physiologist, a physician will be available for all three of your sessions.

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or serious, and can even result in death in some cases. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing.

The risks of a single dose of aspirin are minimal, and because we will carefully screen for any/all conditions that may counter indicate the use of aspirin before enrollment, we do not expect any issues to arise as a result of pills taken for use in this study. Furthermore, the dosage being given is the standard dose taken for, e.g., a headache (650mg). Aspirin may increase the risk of bleeding.

The risks of a single dose of acetaminophen are also minimal, and because we will carefully screen for any/all conditions that may counter indicate the use of acetaminophen before enrollment, we do not expect any issues to arise as a result of pills taken for use in this study. Furthermore, the dosage being given is the standard dose taken for, e.g., a headache (650mg).

The risks of a stress test such as the one being conducted in this study on a stationary cycle are:
1. Feel moderate to severe chest pain.
2. Get too out of breath to continue.
3. Develop abnormally high or low blood pressure or an arrhythmia (an irregular heartbeat)
4. Become dizzy.

As heart rate, blood pressure and temperature are all being accounted for, all of these risks are minimized.

Loss of confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.

Benefits

You are not expected to benefit directly from participation in this study. The ultimate benefit of this research is that we better understand how changes in body temperature affect fatigue associated with multiple sclerosis.

Alternative Procedures

The alternative is to not participate.

Confidentiality

Any information obtained during this study and identified with you will remain confidential. Any information that may be of value to your physician for your personal treatment will be shared with your physician, unless you object to this. All information will be stored in locked files and all information in computer data bases will not have your name or any other identifying information associated with it.

The following individuals and/or agencies will be able to look at and copy your research records:
- The investigator, study staff and other medical professionals who may be evaluating the study
- Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB')
- The United States Food and Drug Administration ('FDA') and/or the Office of Human Research Protections ('OHRP')
- If this study is sponsored (money or supplies are being provided), the sponsor of this study, the National Institute of Health (NIH), including persons or organizations working with or owned by the sponsor
- Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.

Columbia University Irving Medical Center has recently implemented a new electronic medical record (EMR) system, which will be shared with Weill Cornell Medical Center and New-York Presbyterian Hospital and its affiliated institutions.

Your participation in this research study will be documented in our new EMR system. Medical records in this system can be viewed by authorized personnel from these institutions. Study monitors and others who provide oversight of the study may also need to access this record.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Research Related Injuries

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the New York Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Columbia University and New York-Presbyterian Hospital (NYPH) are not offering to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Compensation

You will be compensated $100 after the completion of all three study visits. If we pay you by check, we will ask you for your SSN or TIN number. This information will not be disclosed to any collaborators. There is no cost to you for participating in this study. Reportable payments: According to IRS regulations, compensation payments totaling more than $600 in a calendar year must be reported to the Internal Revenue Service (IRS). We will need to obtain your Social Security Number for this purpose. Reimbursement for travel or other study-related expenses are not considered compensation for tax purposes.

Voluntary Participation

Your participation in this study is completely voluntary. You can refuse to participate or withdraw at any time and such a decision will not affect your medical care at NewYork Presbyterian Hospital, now or in the future. Signing this form does not waive any of your legal rights.

Additional Information

If you have any questions or concerns about the study, you may contact Dr. Victoria Leavitt at 212 342 1351.

If you have any questions about your rights as a subject, you may contact:

Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883

Agreement to be Contacted

May we contact you in the future for taking part in a new study related to MS or other inflammatory and neurologic diseases?

YES:_____ NO:_____
Initial Initial

Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

Study Participant
Print Name _____ Signature _____
Date _____

Research Signature Lines

Person Obtaining Consent
Print Name _____ Signature _____
Date _____