MitoQ for Fatigue in Multiple Sclerosis: A Placebo Controlled Trial

NCT04267926

December 19, 2019

Subject Name: _____ Date: _____

Title of Study: MitoQ for fatigue in multiple sclerosis: a placebo controlled trial

IRB Number: e20334/M4337 ICF Version Date: 12/19/19

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?
About the research, call the Research Coordinator at 503-220-8262 x54594.

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call Vijayshree Yadav at 503-494-5759.

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

WHAT AM I BEING ASKED TO DO?
We are asking you to take part in a research study that is being funded by the Department of Veterans Affairs. We conduct research studies to try and answer questions about how to prevent, diagnose, and treat diseases.

We are asking you to take part in this research study because you have Multiple Sclerosis and fatigue.

TAKING PART IN THIS STUDY IS YOUR CHOICE
You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also your choice. You may refuse to sign this consent form and the authorization. However, to participate in this study, you must sign this consent form and the authorization.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

WHY IS THIS STUDY BEING DONE?
This study is being done to answer the following question: Will oral MitoQ, an antioxidant drug, help MS related fatigue? We are doing this study to find a better approach to relieve fatigue for those with MS. We are also looking to see what the best dose is when taking this drug.

WHAT IS THE USUAL APPROACH TO MY FATIGUE?
You may consult your doctor about drugs are available to treat your MS-related fatigue.

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WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?

You may choose to have the usual approach described above.
You may choose to take part in a different research study, if one is available.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?

Your participation in the study will consist of 4 visits and 4 phone calls over a 13-week period. All four study visits take place at Oregon Health Science University (OHSU). Visits will last up to 2 hours. You will be given either the study drug or placebo, 2 capsules, once daily for 12-weeks.

Research activities performed at OHSU will include the following:

1. Physical and Neurological exams
2. Blood draws
3. Research exams such as the 25 foot walk test and two cognitive tests.
4. Questionnaires about MS, mental state and fatigue
5. Urine test (for females)

Details and risks associated with these visits are detailed in the OHSU consent form.

WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

RISKS

We want to make sure you know about a few key risks right now however we provide more below information in the “What are the risks and possible discomforts from participation?” section.

The study drug has been used in other medical conditions such as Hepatitis C and Parkinson’s disease. In the clinical trials of the study drug, most people did not experience discomfort or adverse side effects. The most common side effect includes nausea and vomiting, It is possible that you could experience a side effect that is unknown at this time.

You may be asked questions that are about sensitive or private things you normally do not discuss. The research team will make every effort to protect your information. However, a loss of privacy could occur. If there is information in your medical record or about you that you do not want to share, you should consider this risk before agreeing to take part in this study.

Taking part in this study may mean you need to make more visits to the clinic or hospital. As a result, you may have more travel or personal costs and/or need to take time off from work.

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This study involves a study drug that could harm a fetus and requires all subjects to use a method of birth control that works well. If you are opposed to using any or all forms of birth control (for any reason), you should speak to the study doctor before considering taking part in this study.

BENEFITS

You may or may not benefit from participating in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

Yes, you can decide to stop taking part in the study at any time.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?

You may be removed from the study if the investigator or the sponsor stops the study or you become pregnant, develop serious side effects, your disease gets worse or if you do not follow instructions. If you choose to withdraw there will not be any additional testing needed.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose(s) of this study is to learn about a new drug called MitoQ that may help decrease fatigue in MS treating fatigue.

DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?

Vijayshree Yadav is a researcher on this study and may also be your health care provider. They are interested in both the clinical welfare of their patients who participate in this study and in the conduct of this study overall. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another provider who is in no way associated with this study. You are not under any obligation to participate in any research study offered by your health care provider.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 60 people will participate in this research study at the VA Portland Health Care System.

WHAT WILL HAPPEN DURING THIS STUDY?

All four study visits will take place at Oregon Health Science University (OHSU) Research Center. A more detailed description of each visit is in the OHSU consent form.

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Visit 1, Week 0: Screening and Baseline measurements.
Visit 2, Week 1: Commencement of Treatment.
Phone follow-ups: After Visit 2, we will follow up with you via telephone every two weeks.
Visit 3, Week 7: Safety assessment.
Phone follow-ups: After Visit 3, we will follow up with you via telephone every two weeks.
Visit 4, Week 13: Completion of treatment.

In this study, some people will receive the real study drug, and some will receive a fake drug called a placebo. A placebo is a pill or solution that tastes, looks and smells like the study drug but has no real medicine in it. A placebo is sometimes called a “sugar pill.” The placebo being used contains tapioca powder and microcrystalline cellulose.

This is a randomized study. That means neither you nor your doctor can choose whether you will receive the study drug or the placebo. That will be decided by chance (like tossing a coin, heads could mean you get the study drug and tails that you get the placebo). You have a 66% chance of getting the study drug in this study.

You and the study staff will not know which pill (or dose) you get. The study is done this way because sometimes knowing that you are getting the test drug can change the results of the study. Also, sometimes people get side effects from placebos. Even though no one will know which pill you will get in this study, if you start having serious side effects, for your safety, the study doctors can find out if you are getting the study drug or placebo. Please ask the study doctor for more information if you have any questions about this kind of study.

Your blood sample will be used only for this research and will be destroyed immediately after they are analyzed.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

In addition to the risks described above in the Summary of Key Information about This Study, “What are the risks and benefits of taking part in this study?” section, the following risks could occur if you choose to take part in this study.

You may have some side effects we do not expect because we are still learning about MitoQ.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

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- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The study drug has been used in other medical conditions such as Hepatitis C and Parkinson's disease. In previous clinical trials of oral MitoQ, most subjects have experienced no discomfort or adverse side effects. It is possible, however, that side effects unknown at this time could occur. Side effects that did occur included headache, nausea, dizziness and vomiting. If you notice any of these side effects, you should notify Dr. Yadav for further evaluation.

While the drug is safe, there might be interactions with other drugs (prescription and non-prescription). The investigator will carefully review all of the drugs you are taking before giving you the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the investigator before you take the new drug. You could also have that provider talk to the investigator before prescribing the new drug. Do not take any new over-the-counter or prescription drugs while you are in this study unless you first check with the investigator.

Taking the study drug may involve risks that are unknown at this time. You may have some side effects we do not expect because we are still learning about the role of this study drug in MS. Therefore, it is important to report any health problems that you experience during the course of the study.

(For Women):
You should not become pregnant while participating. MitoQ could affect a fetus in ways that we do not yet know about. If you are sexually active and at risk of getting pregnant, you and your male partner(s) must use one or two methods of birth control that work well, like birth control pills, a patch, long-acting progestins, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell Vijayshree Yadav and your doctor immediately.

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(For Men):
You should not cause a pregnancy while participating in this study. MitoQ could affect a fetus in ways that we do not yet know about. If you are a sexually active male and can cause a pregnancy you must be sure that you and your female sexual partner(s) use(s) a method of birth control that works well, like birth control pills, a patch, long acting progestins, an IUD, or a diaphragm with spermicide, or you must use a condom with spermicide during sexual intercourse. A vasectomy is an acceptable method of birth control. You must do this the whole time you are in this study. If a sexual partner becomes pregnant during the research study, please tell Vijayshree Yadav and your doctor immediately.

Information that identifies you will be used in this study and shared with the research staff. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting ability to get insurance, current or future job status.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: name, birthdate, telephone number, e-mail address, social security number, and medical record number. We will also use Clincard for payment of your participation and will need to disclose your social security number.

In the future, identifiers may be removed, and de-identified information and/or biospecimens about you used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

Your information will be shared with other researchers as part of this study. A code number will be assigned to your information. Only personnel for this study will be authorized to link the code number to you. Other researchers who may receive your information will be given only the code number and will not be given any other information to link the code back to you.

All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the information, unless you provide written permission or unless otherwise required by law.

The study tests will be recorded in a database called REDCap. The REDCap database is password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at OHSU. By signing this informed consent, you give permission for this data to be maintained by OCTRI, which will be responsible for

maintaining the security and confidentiality of the transferred data. In addition, for Veterans health information from your VA medical record, such as MS diagnosis and symptoms may also be part of the of the OHSU record.

Mandatory reporting of suspected child or elder abuse. Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

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 study involves a drug regulated by the US Food and Drug Administration (FDA), the FDA may choose to inspect research records that include identifiable medical records, identifying you as a subject of this study.

Possibility of Disclosure and Notice of Privacy Practices.
The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048).

If you are a non-Veteran, we will provide you with the VA Notice of Privacy Practices and ask you to sign the acknowledgment (VA Form 10-0483) you received the document. This acknowledgement may be scanned into your medical record.

WILL I BE TOLD ABOUT ANY STUDY RESULTS?
The results will be placed in your OHSU medical record. You will not know if you received the placebo or MitoQ until the entire study is completed and all analysis is performed. We will then contact you and let you know which group you were in.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
A VA participant will not be required to pay for care and services received as a subject in a VA research project. None of the participants will pay for the Study Drug because they are only for research study purposes:

Some Veterans are also required to pay co-payments for medical care and services provided by VA ***that are not part of this study*** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

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WILL ANYONE PROFIT FINANCIALLY FROM THIS STUDY?

Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to an individual, the federal government or a private entity. There are no plans to provide financial compensation to you should this occur. However, should the VA ever provide your samples for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the CONFIDENTIALITY section of this document.

WHAT WILL HAPPEN IF I AM HURT?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.

The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at (503) 412-4580. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

To withdraw, you must write to Vijayshree Yadav at: Neurology Service (p3NEUR) Department of Veterans Affairs VA Medical Center, 3710 SW US Veterans Hospital RD, Portland OR 97239. or ask a member of the research team to give you a form to withdraw your consent. If you withdraw your consent, you may not be able to continue to participate in the study.

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Signature

Vijayshree Yadav or another member of the study team has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. Vijayshree Yadav (503) 494-5759 from 8AM – 5PM, Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my information and specimens as described in this form. In the future, if I decide that I no longer wish to participate in this research study, I agree that my information and specimens which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

_____

Printed Name of Subject

_____ _____ _____

Signature of Subject Date Time

_____

Printed Name of Person Obtaining Consent

_____ _____ _____

Signature of Person Obtaining Consent Date Time