Prevalence of Thiamine Deficiency in Hospitalized Non-Alcoholic Veterans

NCT05480943

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Department of Veterans Affairs

RESEARCH CONSENT FORM
Version Date: 6/24/2024

Participant Name: _____Date:_____
Title of Study: Prevalence of Thiamine Deficiency in Hospitalized Non-Alcoholic Veterans
VA Facility: VA Sierra Nevada Healthcare System

PATIENT INFORMED CONSENT

TITLE: Prevalence of Thiamine Deficiency in Hospitalized Non-Alcoholic Veterans

PROTOCOL NO.: IRB Protocol # 1867369

SPONSOR: VA RR&D Small Projects in Rehabilitation Research

Participant Name: _____ Date:_____

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VA Facility: Sierra Nevada Health Care System

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study about thiamine (vitamin B1) deficiency and how it affects your health. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn how many Veterans who need to be in the hospital don't have enough thiamine in their blood to support healthy nerves and heart.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will last while you are in the hospital if you have no symptoms of thiamine deficiency. If you do have symptoms or your blood test shows low vitamin levels, we will prescribe thiamine and ask to see you back in 3-4 weeks after taking the vitamin. That will be the only extra visit for this study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

To help us understand how many veterans have this vitamin deficiency when they are admitted to the hospital. This will help doctors be aware of this problem. If you have this vitamin deficiency, we will treat you and you will get better from it.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not like to talk to another provider during your hospital stay and have an extra physical exam. There will be blood drawn but most of the time we can combine our tests with those ordered by your treatment team, so it won't involve an extra blood draw.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is a Principle Investagator at the VA Sierra Nevada Healthcare System.

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn how many veterans who are sick enough to need hospitalization suffer from thiamine deficiency. Thiamine deficiency causes mental confusion and distress, weakness in the body, loss of heart function, leg swelling, and upset stomach. Many of these symptoms cause people to go to the hospital. This deficiency can happen if you don't eat a variety of foods that contain thiamine. It can also happen if a person drinks too much alcohol. Currently it isn't known how many non-alcohol drinkers suffer from thiamine deficiency in the United States which is what we want to find out. We think it is much more common than most people think. If we are able to prove it, we can educate everyone that it is something a doctor should think about when someone comes to the hospital for these kinds of problems.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2 years. Your individual participation in the project will take 2 days while you are in the hospital. If we are concerned you might have thiamine deficiency and recommend you take a thiamine supplement, your participation would take 4 weeks including one follow up visit in our clinic.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

The first step is meeting with our research coordinator to review this consent and, if you want to participate, sign this and some other forms.

Next the study team will order blood tests in the morning, to be combined with tests your hospital doctors have ordered already. This will not result in an extra "poke" by the lab technician, but a few extra tubes of blood will be drawn.

Then you will meet with our study doctor or trained health science specialist (a nurse practitioner or physician assistant) who will ask you questions about your diet, how you feel,

where you live, and if you get enough to food to eat. You may also talk to a dietician (nutrition expert) about the kinds of food you eat. Then you will be examined looking for signs of thiamine deficiency. This will happen while you are in the hospital. We expect this to take between one and two hours.

If we think you might have the deficiency, and the symptoms are serious (like mental confusion or you can't walk), we will ask your hospital doctor to start giving you thiamine through your IV (a flexible tube for withdrawing or introducing fluids, put under the skin or into a vein using a needle). If the symptoms are not severe but they are present, we will give you the thiamine by pill when you are discharged from the hospital and ask you to take it once a day for 2 weeks.

If we do not think you have thiamine deficiency, you will be done with the study after you meet with us in the hospital and your blood is drawn. We will send you your test results in the mail. If for some reason your test results show you do have thiamine deficiency, we will call you and start you on thiamine tablets.

The last step is meeting with us again at the VA in Reno after you have taken thiamine for at least 2 weeks so we can talk to you and do another physical exam. We will order a blood test to confirm your deficiency has gone away. We expect this to take an hour.

Throughout the study, if you have any unusual symptoms after we start you on thiamine, you can call the study coordinator and tell us what is going on. Generally, thiamine is very safe with few side effects.

You would be responsible for allowing us to draw the extra tubes of blood and let us to talk to you and examine you in the hospital. If we think you have thiamine deficiency, we expect you would take the thiamine supplement once a day for 2 weeks. Lastly you would be responsible for coming back to see us if we gave you thiamine to take so we can recheck your symptoms and do another physical exam. If you miss your appointment, contact our study coordinator to reschedule. While participating in this research study, do not take part in any other research project without approval from us. This is to protect you from possible injury from things such as extra blood drawing or potential medication interactions. It may also invalidate the results of this study, as well as that of the other study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Blood draw:
There may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood. In most cases we will be able to combine our tests with those already ordered by your hospital doctor to decrease this risk associated with our study. Most of the time bruising and pain can be managed by stopping the procedure and applying pressure to the area.

Interview and physical exam:
Occasionally, additional time spent with our team who will be asking questions and examining you may cause you to be upset. If this happens, we can stop and come back later, or you can withdraw from the study.

Taking thiamine supplements:
If we determine you should take thiamine, there is a rare chance (less than 1%) you might have an allergic (bad) reaction to it. This can include an itchy bumpy rash (hives), a prickly flushing sensation in the skin, sweating, nausea, feeling weak, or feeling restless. If any of those things happen, stop the supplement and call the study coordinator or report to the emergency room if the reaction is severe. If you are unable to take the thiamine for the full 2 weeks due to an allergy, we will withdraw you from the study.

Confidentiality Risks:
Every effort will be made to keep all research information obtained from your samples confidential, but absolute confidentiality cannot be guaranteed. Your laboratory data obtained from blood samples will appear in your medical record for review by VA medical providers. Some of the research information obtained as a result of your participation in this study will be included in your medical record or given to your doctor. Information from which you may be personally identified will be maintained in a confidential, locked file and will not be disclosed to third parties except with your permission or as may be required by law. A progress note will be included in your medical record that you are participating in a research project.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive in the hospital are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of your hospital care.

The safe use of thiamine in pregnant women and nursing mothers has been well established. In fact, thiamine supplements are important to a mother's health (and that of your baby) if you are or may become pregnant. If, while participating in the study, you suspect you have become pregnant, please notify the study coordinator immediately. Women are considered to be able to become pregnant unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are post-menopausal, that is, no menstrual period for more than 6 months.

HOW WILL MY IDENTITY BE PROTECTED?

Your blood samples will be labeled with your personal identifiers (social security number, name, date of birth) as are all the blood samples that go to the lab. These samples will be sent for routine processing at the lab (both local VA lab and LabCorp and Quest). The blood tubes are destroyed once your samples are analyzed. Your study doctor and the researchers will make every effort to protect your identity. None of your personal information will be stored with the research results and will not be shared with anyone outside of the research team.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefit from taking part in this research study. However, it is possible that you may have improvement of some of your symptoms if you have low thiamine levels. If we find out you have other vitamin deficiencies besides thiamine, we will let your treatment team know to begin replacing them so you feel better. Other benefits include helping us promote better health for all Veterans by increasing awareness of this problem.

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WHAT IS THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study. If you are scheduled for a follow up visit, you will have to pay for travel to and from the hospital.

WHAT WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Upon completion of your lab test and visit with the doctor or health sciences specialist during your hospital stay, we will pay you $30. If we think you have symptoms of thiamine deficiency while in the hospital, we want to see you for a visit after taking thiamine tablets for 2-3 weeks. If you come to that visit, we will pay you $200, there is the potential for a maximum payment of $230 for participating.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

It is very unlikely you will be injured while taking part in this study. If you do, the VA will take care of any medical problems that arise as part of your routine care.

If you should have a medical concern or get hurt or sick because of taking part in this study, call:

DURING THE DAY:

Clinical Research Coordinator Team

AFTER HOURS:
Leave a message for the study coordinator

VA Nurse Advice line

Emergency and ongoing medical treatment will be provided as needed.

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DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is completely voluntary. Refusal to take part will not result in any penalty or loss of VA benefits which you are already receiving. If you are an employee it will not influence your employment, ratings, or subsequent recommendations.

You may stop taking part at any time without penalty or loss of VA healthcare benefits. If you withdraw you will still receive the same standard of care that you would otherwise have received. If the study team determines you may have symptoms of thiamine deficiency and you withdraw from the study, we will advise your primary treatment team to continue the thiamine supplement which you might benefit from. For data already collected prior to your withdrawal, the study team may continue to review the data already collected but cannot collect further information, except from public records, such as survival data. This includes blood specimens already drawn for vitamin levels.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The study team may remove you from the study if we are unable to collect blood specimen for the study or you are unable to attend the follow up visit. This would only happen after multiple attempts to contact you including sending you a certified letter.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

Please call our research coordinator.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB) . This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the research department if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Any new findings developed during the research that may affect your willingness to continue participation will be provided as soon as possible in person or by phone. We will also advise you of your blood test results either by phone or by a letter. If your thiamine level is low and you have not already been started on a thiamine supplement, we will call you and start you on it.

WHO COULD PROFIT FROM THE STUDY RESULTS?

No one at the VA will receive payment for this study. No blood specimen will be used for commercial profit and no new commercial products or tests will be developed that would result in anyone making money.

DOES THIS STUDY INVOLVE GENETIC RESEARCH? HOW WILL MY GENETIC INFORMATION BE PROTECTED?

This study does not involve genetic research.

FUTURE USE OF DATA AND RE-CONTACT

The data we gather from your participation in this study will be saved for future research on nutrition and thiamine deficiency without additional consent. Your information will be stored electronically on a protected research computer drive. It will be separated from your name and date of birth to prevent anyone from connecting the data to your personal identification. The only people who will have access to the data is the principle investagtor and her research team who have all been trained in protecting your private information.

No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The research team has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date