

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE-GRIFFIN PREVENTION RESEARCH CENTER

Title of Study: IVMT for Fibromyalgia Syndrome: A Pilot Study

Principal Investigator: David L. Katz, MD, MPH

Funding Source: National Institute of Health's National Center for Complementary and Alternative Medicine

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to investigate the effects of intravenous micronutrient therapy (IVMT) in adults with fibromyalgia (FMS). Approximately 40 adults will participate in the study. You have been asked to participate because you qualify based on study criteria. You can speak, read and write English. To your knowledge, you do not have: any other rheumatologic disease, chronic infections, untreated endocrine disorders, unstable seizure disorders, previously diagnosed psychiatric disorders, acute peptic ulcer disease, congestive heart failure, chronic liver disorders and/or bleeding diathesis, or a known allergy to shellfish or thiamin. You are not pregnant. If you take any prescription drugs for FMS, you have been on a stable dose for a minimum of three months, or agree to stop taking any FMS medication for the duration of the study. You do not take narcotics; however, if you do take narcotics, you are willing to give up the medication in question at least 30 days prior to study enrollment and for the duration of the study.

If you are under the care of a physician for FMS and on prescription medication, you will be asked to obtain written documentation from your physician that discontinuation of medication is acceptable and safe, or that dosing has been stable for a minimum of 3 months, should you wish to enroll in the study. If you currently take vitamins/minerals, you will be asked to discontinue all supplement use throughout the course of the study. If you use any other modalities of treatment specifically for FMS, such as acupuncture or osteopathy, you will need to discontinue use prior to enrollment.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, you will be asked to come to the Integrative Medicine Center at Griffin Hospital to have a clinical screening appointment, consisting

of a brief physical examination by a rheumatologist who will assess your FMS by measuring overall tenderness at 18 tender point sites. If you are deemed eligible at this point, you will undergo a skin test to determine if you are allergic to anything in the IVMT solution, specifically thiamin. If you exhibit signs of allergic reaction, you will be excluded. You can request a copy of this information for your personal records and have it sent to your doctor if desired. Before you are enrolled in the study, you will keep a diary of your FMS-related medication use and present it to the study coordinator at the end of two weeks. Once enrolled in the study, you will be assigned to one of two treatment groups: IVMT or placebo.

We will decide what treatment you will receive by random selection. This means that your treatment will be decided by the luck of the draw and not selected deliberately because of any specific characteristics or problems you have. The study will be double-blinded, which means that neither you nor the researchers involved will not know which treatment you are receiving. At the end of the study, your treatment assignment will be revealed to you.

The intervention will last for eight weeks. During this time, you will receive IVMT or placebo once a week, for a total of eight treatments. Each appointment will last approximately 30 minutes.

During the course of the study, a study coordinator will call you to arrange appointments for your follow-up assessments. You will have an assessment before you begin the intervention, at the end of the eight-week intervention, and once more three months after the end of the intervention. At each of the assessments, you will come to the Integrative Medicine Center. At each visit, a rheumatologist will perform a tender point examination of the 18 specific tender point sites. You will also be asked to fill out three questionnaires assessing your FMS, psychological status and quality of life. Your participation in this study will, in no way, affect your normal medical treatments.

Risks and Inconveniences

The nature of this entire procedure makes it safe and without significant risks. However, you will have an intravenous procedure, which may result in temporary discomfort. Allergic reaction to thiamin is a safety issue to be considered. This is avoided by the administration and observation of a skin test consisting of a small amount of thiamin, and will be done at the time of the initial screening. Also, those who report an allergy to shellfish will be excluded from this trial to avoid a possible reaction to the calcium gluconate. You may contact Alyse Sabina, MPH, at 203-732-1368 or any other member of the study team if you experience any research-related complications.

Benefits

You will benefit by receiving detailed information regarding your FMS. The information gathered by this study may help identify an effective and safe treatment for FMS that would provide tremendous benefit to the thousands of sufferers of this condition, in addition to relieving an ineffective and overburdened healthcare system.

Economic Considerations

You will not be compensated financially for your participation in the study. All study procedures will be provided at no cost to you. Travel expenses will not be reimbursed; however, parking and valet service will be provided free of charge. Furthermore, the study investigators may terminate your involvement in the study if you do not follow the study protocol or if you develop any health conditions, or begin any medical treatments, that may affect your eligibility. Your decision whether or not to participate will not affect any future medical care at Griffin Hospital.

Treatment Alternatives/Alternatives

Your participation in this research study will involve adding an alternative medicine treatment to your standard treatment for FMS. You may continue taking FMS medications if you have been on a stable dose for the past three months, or you may discontinue use of FMS medications, provided that your physician deems that discontinuation of medication is acceptable and safe should you wish to enroll in the study. Your alternative to participating in this study is to continue with your current treatment plan.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. In all records of this study, a number will identify you and only the researchers will know your name. All records will be stored in locked file cabinets at the Yale-Griffin Prevention Research Center, and all electronic files will be password-protected. Data will be kept for five years after the study ends and will be destroyed at that point. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Griffin Hospital Institutional Review Board or Yale Human Investigation Committee may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential. Also, authorized representatives of the Food and Drug Administration (FDA) or National Institute of Health (NIH) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Use and Disclosure of Your Protected Health Information: what information will be used or disclosed

By signing this form, you are authorizing the use and disclosure of your health information collected in connection with your participation in this research study. Your name, address, phone number, date of birth, and social security number will be used to enroll you in the study, but once enrolled, you will be assigned a number which will identify you for the remainder of the study. Your ID number may be used or disclosed by Griffin Hospital and Yale University labs, the Principal Investigator (Dr. David Katz), the

study Co-Investigators (Dr. Adam Perlman), the Data Manager (Dr. Valentine Njike), the study coordinator (Alyse Sabina), the study research assistant (Lauren Liberti); other members of the study team as designated and approved by the principal investigator; Dr. Brian Karsif, Griffin Hospital IRB Chairman; and the National Institutes of Health. The purpose of the use or disclosure of this information is for your participation in the **IVMT for Fibromyalgia Syndrome** study.

By signing this consent, you authorize the use and/or disclosure of your protected health information as described above. If you do not agree to use or disclosure of the information as described and therefore do not sign this consent you may not be in the study. If, after signing the consent, you change your mind, you have the right to revoke your consent in writing, and you will be withdrawn from the study. Once protected health information is disclosed, it is subject to re-disclosure by the recipient, and no longer can be considered protected. You may obtain a copy of the Griffin Hospital Privacy Notice for a complete description of the Hospital's privacy practices for protected health information.

Investigator Compensation

The Institutional Review Board (IRB) of Griffin Hospital has requested that the Investigators disclose to you, the study participant, the nature of any and all compensation received from the National Institutes of Health (NIH), the study sponsor to conduct the study. Accordingly you should know that the investigator is being paid a standard fee directly by the NIH to recruit study participants and to conduct the research. However, there is no other financial relationship between the investigator or members of his family and the NIH. This includes any proprietary interest such as patents, trademarks, copyrights or licensing, equity interests or grants, consulting fees, honoraria, or equipment. The Griffin Hospital IRB has determined that this level of compensation does not pose a significant conflict of interest in the performance of this study.

In Case of Injury

If you are injured as a result of your participation in this study, the research staff at the Yale-Griffin Prevention Research Center will be available to assist you. The investigators and the NIH will not provide additional money or insurance coverage to compensate you if you are injured or if you experience adverse effects during this study. If you are injured or if you experience adverse effects as a result of this study, appropriate arrangements will be made to treat your medical condition, such as referral to a physician. You will have to contact your own insurance company or arrange other independent means to pay for any medical treatments. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

Voluntary Participation and Withdrawal

Your participation in this study is voluntary and you may refuse to participate and/or withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Should you decide to withdraw from the study you would contact Alyse Sabina either by phone at: 203-732-

1368, or in writing to: The Yale-Griffin Prevention Research Center, 130 Division Street, Derby CT, 06418. The study investigators may terminate your involvement in the study if you do not follow the study protocol or if you develop any health conditions, or begin any medical treatments, that may affect your eligibility. Your decision whether or not to participate will not affect your current or future medical care at Griffin Hospital.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully — as long as you feel is necessary — before you make a decision. Questions about this study should be directed to (the PI) Dr. David Katz at (203) 732-1265; questions regarding your rights as a research subject may be directed to Dr. Brian Karsif, Chairman of the Institutional Review Board (IRB) at Griffin Hospital (203-732-1447). Should you wish to file a complaint, you can do so by contacting Griffin Hospital's Privacy Officer, Edward J. Berns, Esq., in writing at 130 Division Street, Derby, Ct 06418 or by telephone at (203) 732-7506, if you believe your privacy rights have been violated.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name: _____

Signature: _____

Date: _____

Signature of Principal Investigator/Person Obtaining Consent

Date

July 9, 2004

