Informed Consent

Title of Research Project: Role of Magnesium Supplementation in the Treatment of Depression

Principal Investigator: Emily Tarleton MS, RD
Faculty Sponsor: Benjamin Littenberg, MD

You are being invited to volunteer for this research study because you have a history of depression. The purpose of this study is to look at the effect of magnesium supplementation on depression. This informed consent form provides you with information that you should know and understand before agreeing to be in the study.

After reading this informed consent form, you will be able to ask any questions that you may have. You may take home a copy of this informed consent form to think about or discuss with family and friends before making your decision.

Why is This Research Study Being Conducted?

Depression is a common and disabling condition. Magnesium supplementation has been linked to improvement in depression and low magnesium levels have been associated with worse depression. The purpose of this study is to determine what role magnesium supplementation plays in changing symptoms of depression.

How Many People Will Take Part In The Study?

We are recruiting about 100 adults with mild to moderate depression.

What Is Involved In The Study?

We will ask you about your health, what medications you take, and how you are currently treating your depression. All information will be kept private and only the study team will have access to this information. All of your information will be given a code and your name and any identifying information will be removed.

This study takes place over 12 consecutive weeks. While we will follow you for the full 12 weeks, you will only take magnesium tablets for 6 consecutive weeks. You will be randomly assigned to start the supplement at week 1 or week 7. The tablets will be provided free of charge.

What is expected of you throughout the study?

- Complete an in-person baseline interview (approximately 45 minutes, not including travel time).
- Take the magnesium chloride tablets twice daily for either the first or second 6 weeks of the study period.

- Complete brief telephone interviews every 2 weeks, which includes two questionnaires about depression and anxiety (approximately 10 minutes per call).
- If you are taking the supplements beginning with week 7, you will need to meet with someone form the study to pick up your supplements. We will arrange a time and place to meet that is convenient for you (approximately 10 minutes, not including travel time).
- If you find out that you are pregnant during the study you should contact the PI as soon as it is convenient for you. If you are taking the supplements when you find out please stop the supplements. We will continue to follow up with you every two weeks for the duration of the study.

If you decide to participate in this study, we will include the answers that we collect from your questionnaires and phone calls in your research record.

Below is a table showing the timeline of the study and what will happen each week.

Week	Baseline	1	2	3	4	5	6	7	8	9	10	11	12
Questionnaire	x												
Patient Health Questionnaire-9	x		x		x		x		x		x		x
Generalized Anxiety Disorder-7	x		x		x		x		x		x		x
Phone call			x		x		x		x		x		x
Tablets Provided	x*							x*					

* Tablets provided either at baseline or week 7.

What Are The Benefits of Participating In The Study?

It is possible that the magnesium tablets will improve your symptoms of depression. You may help us learn more about how to help people with depression.

What Are The Risks and Discomforts Of The Study?

- Magnesium tablets can cause physical side effects including nausea and diarrhea.
- It is important that you take the tablets as instructed. If you take more magnesium than is prescribed there is a risk for magnesium toxicity. Signs of magnesium toxicity include:
  - Low blood pressure
  - Nausea
  - Vomiting
  - Retention of urine
  - Facial flushing
  - Irregular heartbeat
  - Cardiac arrest
- Your depression might worsen. **If you feel that your depression is worsening and that you may be at risk for hurting yourself, stop the tablets immediately and seek help either by dialing 911 or going to the emergency room. You should also contact**

your healthcare provider or contact the suicide prevention lifeline (1-800-273-TALK).

- There is a risk of accidental loss of confidentiality; however, all research data will be stored in a locked office or password protected if stored on the computer. (See "What About Confidentiality?")

It is important that you promptly tell the researcher, Emily Tarleton, if you believe that you have been injured because of taking part in this study. You can call her at 802-847-4730 or 802-999-1492 or email Emily at Emily.tarleton@uvm.edu.

More information about magnesium can be found at the National Institutes of Health website: http://ods.od.nih.gov/factsheets/Magnesium-Consumer/

Are There Any Costs?

There will be no cost to you for your participation in this study. Magnesium tablets will be provided free of charge.

This study is being funded through The University of Vermont Clinical and Translational Science department funds.

What Is the Compensation?

There is no compensation associated with participation.

What About Confidentiality?

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

To minimize the risks to confidentiality, we will keep all research data in a locked office at The University of Vermont Medical Center or on a password protected database.

The Institutional Review Board and regulatory authorities will be granted direct access to your original research records for verification of research procedures and/or data.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

We will ask for your email address as a secondary means of reaching you if we cannot reach you by phone. Please note that email communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse, or intent to harm yourself or others.

Please refer to the separate Authorization Form that explains more specifically how your personal health information will be used.

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.

Commercial Issues

There are no plans to compensate you for the use of any findings of the future research studies conducted using the information in the study.

What Happens If You Are Injured?

If you have side effects from the magnesium tablets or have an increase in depressive symptoms, stop the magnesium tablets right away. If you feel that your depression is worsening or that you may be at risk for hurting yourself you should stop the tablets immediately and seek help either by dialing 911 or going to the emergency room. You should also contact your healthcare provider or contact the suicide prevention lifeline (1-800-273-TALK).

UVM Medical Center Policy

If you are injured or become ill as a result of being in this research, The UVM Medical Center, the hospital partner of the University of Vermont, will provide reasonable and usual medical care for that injury or illness. There will be no cost to you if the conditions listed below apply to your injury or illness. These conditions are:

1.The investigator, in consultation with the study sponsor, determines that your injury or illness results from the research and not from your underlying condition or its usual treatment.
2.You let the investigator know about the injury or illness when you first notice it; and
3.You follow medical advice about proper treatment options for the injury or illness.

The UVM Medical Center may claim payments for your medical treatment directly from the study sponsor or your insurance company when these payments are allowed.
For an injury or illness that results from being in this study, the University of Vermont and The UVM Medical Center will not offer you any other payments, such as lost wages or expenses, except for your medical care. Even though you may receive medical care at no cost to you under certain conditions if you are in this study, the UVM Medical Center and the University of Vermont do not admit to any responsibility for an injury or illness that results from being in the

study. If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What Other Options Are There?

There are several treatments for depression. You should talk with your doctor about what treatment is right for you. You and your doctor might find that medication or therapy is needed at this time to help you with your depression. If you choose to start therapy or medication, or change your current medication, you are no longer eligible for this study. Once you are on a stable treatment as prescribed by your doctor, you may once again be eligible to participate.

Can You Withdraw or Be Withdrawn From This Study?

You may discontinue your participation in this study at any time. If you withdraw before the end of the study your data up until that point may still be used for research purposes.

The researchers may discontinue your participation in this study at any time. If at any point the researchers feel your depression is worsening or that you are at risk of hurting yourself, they may discontinue your participation and refer you to your healthcare provider.

What if you decide not to give permission to use and give out your health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you will not be eligible to participate in the study.

May I revoke (take back) my permission?

Yes. To revoke your permission, please write to the study investigator:
Emily Tarleton, MS, RD
UVM Clinical Research Center
MCHV Campus Shep 201
111 Colchester Ave
Burlington, VT 05401

Contact Information

You may contact Emily Tarleton, MS, RD, the Investigator in charge of this study, at 802-847-4730 for more information about this study. If you have any questions about your rights as a participant in a research project, or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study, you should contact the Director of the Research Protections Office at the University of Vermont, at 802-656-5040.

Statement of Consent

To be in this study, you must sign this page. By signing this page, you are voluntarily agreeing to be included in this study.

Before signing, you should be sure of the following:

- You have read all of the information in this "Informed Consent" form (or had it read to you).
- You have had the chance to ask questions about the study, and your questions were answered.
- If you did not understand any of the answers to your questions, you asked a staff member to explain them to you.
- You have had time to think about the information and decide whether or not to be in the study.

If you decide to be in this study:

- You are allowing your health information collected by the investigator to be included in the study.
- You are agreeing to take the tablets provided for 6 weeks.
- You are agreeing to fill out or answer the study questionnaires and to speak to a study representative every two weeks.
- You may freely choose to stop being in the study at any time.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

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Signature of Subject **Date**

This form is valid only if the Committees on Human Research's current stamp of approval is shown below.

_____

Name of Subject Printed

_____

Signature of Principal Investigator or Designee **Date**

_____

Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Emily Tarleton, MS, RD
Address: UVM Clinical Research Center
MCHV Campus, Shep 201
Burlington VT, 05403
Telephone Number: 802-847-4730

Name of Faculty Sponsor: Benjamin Littenberg, MD
Address: General Internal Medicine
Given Courtyard S459
Burlington, VT 05401
Telephone Number: 802-656-4560

AUTHORIZATION FORM

Permission for the Use and Disclosure of Health Information for Research

TITLE OF STUDY: Role of Magnesium Supplementation in the Treatment of Depression

PRINCIPAL INVESTIGATOR NAME: Emily Tarleton, MS, RD
ADDRESS:111 Colchester Ave, MCHV Campus Shep 201, Burlington VT 05401

CHRMS/CHRBSS NUMBER:M15-337

You have been asked to take part in the research study listed above. This form asks for your permission to use your health information for this study and disclose it to others who need it for their work in this research. If you sign this form, you are giving us permission to use and disclose your health information for research as described below.

The purpose of this study is to look at the effect of magnesium supplementation on depression.

What health information will be used and disclosed for this study?
The health information we plan to collect for this study is listed below.

- Medical history.
- Information that identifies you, such as your name, address, age, and sex.
- Lists of medications you are taking

Who is disclosing your health information for this research study?

- You will provide most of this information to us. We will not look at your medical record.
- The University of Vermont Medical Center
- Other doctors' offices and hospitals where you may receive medical care while this study is active.

Who will use your health information in this study?
Our research team will use your health information. We may also share it with those who assist with the conduct of the research or oversight of the activities for this study. The representatives from the institutions, organizations, and agencies are listed below.

- The University of Vermont and its Committees on Human Research
- The University of Vermont Medical Center

Federal law usually protects the confidentiality of your health information. Once your health information is disclosed in this study, these laws may no longer apply. As a result, your health information could be further disclosed for other purposes. It is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

How long will your health information be used for research?
Your permission to use your health information will not end until the study is completed. During this study, you will not have access to study data. You may ask for your data once study activities are complete. You have a right to receive a copy of the information in your medical record at any time.

What if you decide not to give permission for research use of your health information?
If you decide not to allow the use and disclosure of your health information, you may not take part in this study. Your decision will have no effect on your current or future medical care.

If you later choose to stop taking part in this study in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission.

Who can answer your questions about the use and disclosure of your health information?

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at 802-847-4730 or the Privacy Officer at The University of Vermont Medical Center, Inc. Michael Hawkins, at (802) 847-3532.

I have read the information in this form and my questions about it have been answered. By signing this form, I agree to allow the use and disclosure of my health information for the research described above. I expect that a copy of this form will be given to me for my records.

Subject's Name [print]	[Signature]	Date
Person obtaining authorization [print]	[Signature]	Date

*For individuals who lack capacity to give permission, the personal representative identified below is providing authorization.

Subject Representative [print]	[Signature]	Date

* If a personal representative signs the authorization, a description of that representative's authority to act for the subject is described below.

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Committee on Human Research
Date 4/15/2015