Magnesium Sulfate Versus 5% Dextrose With Treatment Resistant Depression

This study is currently recruiting participants.
Verified May 2012 by University of Miami

First Received on May 9, 2012. Last Updated on May 10, 2012 History of Changes

Sponsor:	University of **Miami**
Collaborator:	Life Extension Foundation
Information provided by (Responsible Party):	John E. Lewis, University of Miami
ClinicalTrials.gov Identifier:	NCT01597167

Purpose

The proposed study is a 1-week, randomized, double-blind, placebo-controlled, trial to evaluate the efficacy of an IV infusion of magnesium sulfate on symptoms of treatment resistant mild and moderate **depression** in 20 males and females (21-70 years of age). Participants will be assessed at screening/baseline, day 1, day 2, day 7, and day 8. Each subject will be randomized in a double-blind fashion to receive either IV infusion of magnesium sulfate or 5% dextrose followed by a washout period of 5 days then crossover to receive either IV infusion of 5% dextrose or magnesium sulfate.

Condition	Intervention
Depression	Dietary Supplement: Magnesium sulfate

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Crossover Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Double-blinded Randomized Study of IV Infusion of Magnesium Sulfate Versus 5% Dextrose in a Crossover Design in Male and Female Volunteers With Treatment Resistant **Depression**

Resource links provided by NLM:

MedlinePlus related topics: Depression

Drug Information available for: Magnesium Magnesium sulfate Dextrose

U.S. FDA Resources

Further study details as provided by University of Miami:

Primary Outcome Measures:

- Magnesium levels in treatment resistant mild and moderate **depression** [Time Frame: 8 days] [Designated as safety issue: No]

  To investigate the magnesium deficient status in treatment-resistant mild and moderate depression patients via assay of 24-hour urine magnesium, blood magnesium, and EXATEST of intracellular magnesium of epithelial cells before and after IV infusion.

- Self reported **depression** measures [Time Frame: 8 days] [Designated as safety issue: No]

  To assess the effectiveness of the magnesium sulfate infusion on the mean change in scores on the Hamilton Rating Scale for Depression and the Patient Health Questionnnaire (PHQ-9) for depression.

Secondary Outcome Measures:

- Correlation of magnesium levels with self reported measures of **depression** [Time Frame: 8 days] [Designated as safety issue: No]

  To correlate the levels of magnesium with the scores on the Hamilton Rating Scale for Depression and the Patient Health Questionnaire (PHQ-9) for depression

Estimated Enrollment:	20
Study Start Date:	October 2011
Estimated Study Completion Date:	March 2013
Estimated Primary Completion Date:	December 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Magnesium sulfate crossover IV infusion of magnesium sulfate followed by 5-day washout period and crossover to 5% dextrose (placebo)	Dietary Supplement: Magnesium sulfate 4 grams magnesium sulfate in 100 ml IV over 4 hours
Placebo Comparator: Placebo crossover IV infusion of 5% dextrose with 5 day washout and crossover to magnesium sulfate	Dietary Supplement: Magnesium sulfate 4 grams magnesium sulfate in 100 ml IV over 4 hours

Detailed Description:
Purpose:

1. To determine the magnesium deficient status in treatment-resistant mild and moderate depression patients via 24-hour urine magnesium assessment before and after IV magnesium infusion.
2. Correlation of intracellular magnesium (EXATEST), urine magnesium, and serum magnesium as well as sensitivity to the IV magnesium infusion.
3. To assess the effectiveness of magnesium sulfate infusion on treatment resistant mild and moderate depression patients.

Objectives:

Primary:

1. To investigate the magnesium deficient status in treatment-resistant mild and moderate depression patients via assay of 24-hour urine magnesium, blood magnesium, and EXATEST of intracellular magnesium of epithelial cells before and after IV infusion.
2. To assess the effectiveness of the magnesium sulfate infusion on the mean change in scores on the Hamilton Rating Scale for Depression and the Patient Health Questionnaire (PHQ-9) for depression.

Secondary:

1. To correlate the levels of magnesium with the scores on the Hamilton Rating Scale for Depression and the Patient Health Questionnaire (PHQ-9) for depression.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

1. Potential participants must be English speaking.

Exclusion Criteria:

1. Currently enrolled (or have been in the last 30 days) in another research trial for investigative nutritional or other therapies thought to have an impact on depression.
2. Currently taking a medication or nutritional supplement containing more than 100% RDA of magnesium (for women over age 31, it is 320 mg/day and for men over age 31, it is 420 mg/day) and unable to discontinue using it 14 days prior to the Day 1 visit. (Current use must be stopped 2 weeks before enrolling in the study and during trial.)
3. Diagnosed with any medical condition, including diabetes, cardiovascular disease, pulmonary, renal, endocrine, hepatic, neurologic, psychiatric (except for depression), immunologic, hematologic, gastrointestinal, or metabolic disease requiring medical treatment that would preclude participation in the study.
4. Taking Digoxin (used to treat congestive heart failure and to slow the heart rate in patients with atrial fibrillation.
5. Taking penicillamine (also known as Cuprimine or Depen for Wilson's disease or rheumatoid arthritis).
6. Taking any antibiotic (including tetracycline or a quinolone).
7. Taking any psychotropic medication for any indication, except sedatives for sleep such as Zolpidem, in addition to the SSRI in the course of treatment for your depression.
8. Taking a SSRI for less than 90 days or unable to maintain the same therapeutic regimen throughout the study duration.
9. A history of any medical or surgical procedure that would preclude participation in the study.
10. Diagnosed with gastrointestinal disorders that could lead to uncertain resorption of the study supplements.
11. Pregnant, plan to become pregnant, or currently breast feeding.
12. Unwilling to avoid pregnancy (use medically-acceptable birth control method during the study with at least one method for the period of one month prior to beginning of the study until at least three months after study completion or are surgically sterile or postmenopausal (at least 12 months without a period).
13. Systolic blood pressure >160 mmHg or diastolic blood pressure >90 mmHg.
14. Had any of the following abnormal laboratory test values: (a) bilirubin > 2x upper normal limit, (b) AST and ALT > 2x upper normal limit, (c) serum creatinine > 1.5 mg/dl, (d) blood glucose below 80 mg/dl or above 110 mg/dl, (e) calcium level < 8.6 mg/dl, or (f) triglycerides >200 mg/dl.
15. Currently undergoing any chemotherapy or radiation treatment for cancer, have an active malignancy, or have had within the past 5 years any type of malignancy, other than non-melanomatous skin malignancies.

16. A history of substance abuse (e.g., alcohol, opiates, benzodiazepines, or amphetamines).
17. Currently consume more than 6 standard alcoholic drinks a week (A standard alcoholic drink is defined as one bottle/can of beer, one glass of wine, or one ounce of hard liquor.).
18. Diagnosed with a terminal illness.
19. Donated blood in the last 30 days.
20. Any severe, acute illness within the last five days.
21. Currently taking any tricyclic antidepressants.
22. Have a pacemaker or internal medical device.
23. Beck Depression Inventory score less than 13 or greater than 29 or answer to question 9 is something other than "I don't have any thoughts of killing myself"

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01597167

Contacts

Contact: Courtney Avery 305-243-9373 cavery@med.**miami**.edu

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Locations

United States, Florida

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Miami, **Florida**, **United States**, 33136

Sponsors and Collaborators

University of **Miami**

Life Extension Foundation

Investigators

Principal Investigator: John Lewis, PhD University of **Miami**

More Information

No publications provided

Responsible Party:	John E. Lewis, Associate Professor of Psychiatry and Behavioral Sciences, University of Miami
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Other Study ID Numbers:	20110168
Study First Received:	May 9, 2012
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Health Authority:	United States: Institutional Review Board

Keywords provided by University of Miami:
mild moderate treatment-resistant **depression**
magnesium sulfate

Additional relevant MeSH terms:

Depression	Therapeutic Uses
Depressive Disorder	Anesthetics
Behavioral Symptoms	Central Nervous System Depressants
Mood Disorders	Anti-Arrhythmia Agents
Mental Disorders	Cardiovascular Agents
Magnesium Sulfate	Anticonvulsants

Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Pharmacologic Actions
Central Nervous System Agents
Calcium Channel Blockers
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Tocolytic Agents
Reproductive Control Agents

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