ISRCTN16067597 https://doi.org/10.1186/ISRCTN16067597

Comparison of magnesium given by mouth to magnesium given through the vein to treat patients with low blood magnesium

Submission date
23/06/2022

Recruitment status
No longer recruiting

Registration date
25/08/2022

Overall study status
Completed

Last Edited
25/08/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypomagnesemia is when the amount of magnesium in the blood is too low. This can cause nausea and vomiting, sleepiness, muscle weakness, spasms, or tremors. This study will compare treatments for hypomagnesemia, comparing magnesium given by mouth to magnesium given through the vein in its ability to increase the blood magnesium level.

Who can participate?
Adult patients can participate if they are hospitalized and have a low magnesium level, are not taking certain medications (proton pump inhibitors, diuretic use), do not have kidney or intestinal problems, do not have severe infections, are not pregnant, and do not have heart problems happening at the same time.

What does the study involve?
Participants will be allocated to one of three groups, with an equal chance of being in each group (like tossing a coin). Participants in the first group will receive magnesium given by mouth, participants in the second group will receive magnesium given through injection into the vein at a normal rate, and participants in the third group will receive magnesium given through injection into the vein at a slow rate.

What are the possible benefits and risks of participating?
The possible benefits of participating to the individual include potential avoidance of another vein medication. The benefits to society include better understanding

Where is the study run from?
Riverside University Health Systems - Medical Center (USA)

When is the study starting and how long is it expected to run for?
June 2015 to September 2017

Who is funding the study?
Riverside University Health Systems - Medical Center (USA)

Who is the main contact?
Dr Alexander Friedman, alex.friedman@ruhealth.org

Contact information

Type(s)
Principal investigator

Contact name
Dr Alexander Friedman

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of oral and intravenous magnesium repletion in patients with hypomagnesemia: a randomized controlled trial

Study objectives
Repletion with intravenous magnesium is non inferior to oral magnesium in raising serum magnesium level for mild to moderate hypomagnesemia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2015, Riverside University Health System Medical Center (RUHSMC) IRB (26520 Cactus Ave, Moreno Valley, CA 92555; +1 951 486 4098; IRB@RUhealth.org)

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypomagnesemia

Interventions
Participants will be randomized into three groups. The randomization process will involve randomly generated numbers placed in sealed envelopes. Group 1 received magnesium oxide (MgOx) 400 mg tabs: 1600 mg, followed by 800 mg 4 h later. Group 2 received magnesium sulfate (MgSO4) 2 g IV infused over 2 . Group 3 was administered magnesium sulfate (MgSO4) 2 g IV, infused over 6 h.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
magnesium sulfate, magnesium oxide

Primary outcome(s)
Absolute serum magnesium level measured from blood samples collected at the time of enrollment and between 18 and 30 h after initiation of repletion

Key secondary outcome(s))
The relative rise in serum magnesium level measured from blood samples collected at the time of enrollment and between 18 and 30 h after initiation of repletion

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Inpatient at the participating medical center
2. Aged >18 years
3. Serum magnesium between 1.2 and 1.7 mg/dl

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
112

Key exclusion criteria
1. Proton pump inhibitor (PPI) use
2. Concomitant diuretic use
3. Acute or chronic renal insufficiency
4. Active myocardial infarction
5. Eclampsia or preeclampsia
6. Pregnancy
7. Incarcerated status
8. Unable to tolerate oral intake
9. History of bowel surgery
10. Active diarrhea
11. Concomitant chemotherapy
12. Severe sepsis
13. Prior enrollment in the study

Date of first enrolment
10/07/2015

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
United States of America

Study participating centre
Riverside University Health System Medical Center
26520 Cactus Ave
Moreno Valley
United States of America
92555

Sponsor information

Organisation
Riverside University Health System - Medical Center

ROR
https://ror.org/020448x84

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Riverside University Health System - Medical Center

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Dr Alexander Friedman (alex.friedman@ruhealth.org).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Informed consent - English language		25/08/2022	No	Yes
Participant information sheet	Informed consent - Spanish language		25/08/2022	No	Yes
Protocol file			25/08/2022	No	No