INFORMED CONSENT FORM

This Informed Consent Form is for adults who are being hospitalized at Riverside County Regional Medical Center (also known as Riverside University Medical Center) and have met the inclusion and exclusion criteria delineated in the study protocol.

[Name of Principal Investigator] Ali Motabar, MD
[Name of Organization] Riverside County Regional Medical Center (also known as Riverside University Medical Center).
[Name of Sponsor]: none
[Name of Proposal and version]: Comparison of oral and intravenous magnesium repletion in patients with hypomagnesemia: A randomized controlled trial study, version 1

This Informed Consent Form has two parts:
- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction and Purpose of the Research

Dear Sir / Madam,

You are being asked to participate in a medical study. If you should have any questions, you are free to ask either me or anyone else participating in this study that you feel comfortable with. The purpose of this study is to determine how magnesium, a trace mineral necessary for a number of bodily processes, can best be replaced.

Every organ in the body needs a small amount of magnesium to function well, particularly the heart, muscles, and kidneys. It also helps make teeth and bones. Magnesium helps activate many enzymes, contributes to energy production, and helps regulate levels of calcium, copper, zinc, potassium, vitamin D, and other important nutrients.

Magnesium is found in many foods. However, many people in the U.S. probably do not get as much magnesium as they should from their diet. Foods rich in magnesium include whole grains, nuts, and green vegetables. Green leafy vegetables are particularly good sources of magnesium.

Low magnesium is relatively common, but if it is very low, it may affect a number of heart conditions, diabetes, as well as cause imbalances of other electrolytes. The purpose of this study is to evaluate how to best replace magnesium in the human body.

Type of Research Interventions

We will replace the magnesium your body has lost. However, we will do this either orally or through a catheter placed into your arm or leg. The catheter may be used for administration of other medications which are not a part of this study, so you will not have to endure an additional needle placement for this study. Whether you receive the magnesium orally or intravenously will not be decided by us; it will be decided at random.

Participant Selection

We have chosen you as a potential study participant because you are relatively healthy and, although your body is low in magnesium, it has enough magnesium that your low magnesium state is not life-threatening, making it safe for you to receive it orally.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in hospital for low magnesium. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

After receiving the magnesium, your magnesium blood level will be checked 12 hours later through a blood draw, and again 24 hours later. This will conclude your participation in this trial.

Potential Adverse Effects

It is possible to experience some loose stools or diarrhea when magnesium is given orally. If this occurs, your diarrhea will be treated in the same way as it would if you were not in the study; you will be given medications to slow the gut, if it is considered safe to do so.

It is possible to experience some burning when the magnesium is being administered through a vein.

If, after administration of the magnesium, you are found to have a dangerously high level of magnesium (an event that is extremely unlikely), you will be treated in the same way as if you were not in the study; this may include administration of medications called diuretics to make you urinate more, or hemodialysis (blood filtration) if the magnesium level is life-threatening.

Risks

The risks associated with this study are very low. They consist primarily of not receiving enough magnesium, and requiring additional doses of magnesium later.

Benefits

There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There is potential for benefit to the society at large because knowing which method of providing magnesium replacement to patients will make our healthcare system more effective and efficient.

Confidentiality

We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except your doctors, nurses, staff working on this specific project.

Sharing the Results

The knowledge that we obtain from this project may be published in medical journals and presented at meetings. No confidential information will be shared.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this hospital in any way. You will still have all the benefits that you would otherwise have at this hospital. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Dr Ali Motabar, Dr Alex Friedman, Dr Cynthia Fuentes.

This proposal has been reviewed and approved by the Riverside County Regional Medical Center (also known as the Riverside University Medical Center) Institutional Review Board, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact Dr Iqbal Munir, Dr Anthony Firek, or Judi Nightingale, PhD, RN).

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____ Date (day/month/year) _____

If illiterate: A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** Thumbprint of participant

Signature of witness _____

Date (day/month/year) _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures involved in this study. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this certificate has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher / person taking the consent_____

Date _____

Day/month/year