Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of magnesium oxide supplementation on the quality of life of patients with cardiorenal syndrome caused by chronic heart failure with reduced ejection - A single-arm clinical trials

Protocol summary

Study aim
This study will be conducted with the aim of determining the effect of magnesium oxide supplementation on the quality of life of patients with cardiorenal syndrome caused by chronic heart failure with a drop in ejection fraction.

Design
This study was conducted as an interventional case series, and it was conducted before/after, for this reason, it does not have a control group, and it does not have blinding or randomization.

Settings and conduct
This study was conducted on cardio-renal syndrome patients who visit Rasht Heshmat Hospital clinic as an outpatient, and after meeting the entry criteria, they are included in the study and are evaluated through the KCCQ-12 questionnaire and the 6-minute walking test. Then they are given magnesium supplements for 3 months and they are re-evaluated after 3 months.

Participants/Inclusion and exclusion criteria
Entry conditions include patients with heart failure with EF less than 40 along with kidney failure and magnesium less than 2 mg. Conditions of non-entry include esrd patients, dialysis, liver cirrhosis, pregnant mothers and current use of magnesium containing drugs.

Intervention groups
The intervention in this study includes giving 250 mg magnesium oxide supplements 3 days a week for 3 months to cardiorenal syndrome patients and evaluating its effect on their quality of life.

Main outcome variables
Kansas City Cardiomyopathy Questionnaire (KCCQ-12)،6 minute walking test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230723058900N1**
Registration date: **2023-10-19, 1402/07/27**
Registration timing: **prospective**

Last update: **2023-10-19, 1402/07/27**
Update count: **0**

Registration date
2023-10-19, 1402/07/27

Registrant information
Name
Mahdi Mafi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3361 9195
Email address
mahdimafi1999@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-06, 1402/08/15

Expected recruitment end date
2024-11-05, 1403/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of magnesium oxide

supplementation on the quality of life of patients with cardiorenal syndrome caused by chronic heart failure with reduced ejection - A single-arm clinical trials

Public title
Investigating the effect of magnesium supplementation on cardiorenal syndrome

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Outpatients referred to the clinic diagnosed with chronic heart failure (ECO result with EF less than 40%) Patients with renal failure or evidence of renal damage (decrease in GFR below normal for more than 3 months or albuminuria above 30 mg/dl in 24-hour urine) GFR more than 30 mL/min Serum magnesium below 2 mg/dl

Exclusion criteria:
Current treatment with hemodialysis or peritoneal dialysis Donated kidney recipient or kidney donor Coronary artery bypass grafting Previous parathyroidectomy Hyperparathyroidism Current treatment with medication or supplements containing magnesium (antacids) Recent history of treatment with medicine or supplements containing magnesium Any condition that interferes with the absorption of magnesium from the digestive system (short bowel syndrome / chronic pancreatitis) Pregnant mothers, mothers during breastfeeding Allergy to the contents of the medicine Patient participation in other intervention trials Hypothyroidism and hyperthyroidism Patients showing features of other primary kidney diseases Urinary tract infection Any fever associated with infection Active malignancies Liver cirrhosis and chronic alcoholism All people who used cigarettes and other tobacco products ESRD and stage five CKD Laxatives and other nephrotoxic drugs

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Guilan university of medical sciences

Street address
Cardiovascular Diseases Research Center- Dr. Heshmat Heart Center - next to Gilan Province Management and Planning Organization - 15 Khordad St. -Rasht

City
Rasht

Province
Guilan

Postal code
4193955588

Approval date
2023-06-28, 1402/04/07

Ethics committee reference number
IR.GUMS.REC.1402.211

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50.9

ICD-10 code description
Heart failure, unspecified

Primary outcomes

1

Description
Score of patients in the Kansas City Cardiomyopathy Questionnaire (KCCQ12)

Timepoint
Completing the questionnaire at the beginning of the trial and 3 months after taking the magnesium oxide supplement

Method of measurement
Kansas City Cardiomyopathy Questionnaire

2

Description
Measuring patients' performance in the 6-minute walking test

Timepoint
Measuring patients' performance at the beginning of the trial and 3 months after magnesium oxide supplementation

Method of measurement
6-minute walking test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Giving 250 mg magnesium oxide supplements by jalinous Pharmaceutical Company for 3 months with a gap of one day between drug doses.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr.Heshmat hospital
Full name of responsible person
Samira Arami
Street address
Dr. Heshmat Heart Center - next to Gilan Province Management and Planning Organization - 15 Khordad St. -Rasht
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3361 8177
Email
samira523@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Deputy of research and technology of guilan university of medical science-in front of 17shahrivar hospital,St syadati,St Namjo,Rasht ,Iran
City
Rasht
Province
Guilan
Postal code
4144666949
Phone
+98 13 3333 6394
Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Samira Arami
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Cardiovascular Diseases Research Center- Dr. Heshmat Heart Center - next to Gilan Province Management and Planning Organization - 15 Khordad St. -Rasht
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3361 8177
Email
samira523@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Samira Arami
Position
Assistant Professor
Latest degree

Subspecialist

Other areas of specialty/work
Cardiology

Street address
Cardiovascular Diseases Research Center- Dr. Heshmat Heart Center - next to Gilan Province Management and Planning Organization - 15 Khordad St. -Rasht

City
Rasht

Province
Guilan

Postal code
4193955588

Phone
+98 13 3361 8177

Email
samira523@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Mahdi Mafi

Position
Medical intern

Latest degree
A Level or less

Other areas of specialty/work
Cardiology

Street address
Emam khomeini

City
Rasht

Province
Guilan

Postal code
4193955588

Phone
+98 11 3361 9195

Fax

Email
Mahdimafi1999@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available