

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

419395588

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