Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of magnesium and thiamine combination to improve hyperglycemia and insulin resistance in type 2 diabetic patients

Protocol summary

Study aim
Determining the effect of magnesium and thiamine combination to improve hyperglycemia and insulin resistance in type 2 diabetic patients

Design
A controlled, parallel-group, triple-blind, randomized, phase 2 clinical trial on 100 patients. The rand function of Excel software was used for randomization.

Settings and conduct
This research is carried out by the Endocrine Research Center and patients, doctors and statisticians are blind. Patients are randomly divided into two groups, Patients receiving capsules containing magnesium sulfate and thiamine or placebo. The duration of the study is 6 months, and every three months the blood sample will be taken to measure the variables.

Participants/Inclusion and exclusion criteria
Inclusion criteria: male or female type 2 diabetes patients living in Isfahan, over 18 years of age, with a BMI of 18.5 to 30 kg/m2 who are able to communicate and volunteer to participate in the research. and sign a written consent form. Exclusion criteria: pregnancy and breastfeeding, Infection, inflammatory, thyroid, Liver, kidney, cardiovascular diseases, stroke and cancer. Use of insulin, immunosuppressive and anti-inflammation drug Change in the type or dose of diabetes medication during the intervention. Patients who consume less than 90% of the tested drug

Intervention groups
The intervention group: diabetic patients received metformin and capsules containing magnesium sulfate and thiamine, and the control group : diabetic patients received metformin and placebo.

Main outcome variables
HOMA-IR, FBS, HbA1c, GLUT4 and FOXO1 gene expression

General information

Reason for update

Acronym
TMg

IRCT registration information
IRCT registration number: **IRCT20151028024756N4**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date
2023-10-14, 1402/07/22

Registrant information

Name
Nepton Soltani

Name of organization / entity
Hormozgan University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 913 325 1067

Email address
nsoltani@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of magnesium and thiamine combination to improve hyperglycemia and insulin resistance in type 2 diabetic patients

Public title
Effect of thiamine and magnesium sulfate in treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a definitive diagnosis of type 2 diabetes for more than 5 years by a physician (plasma glucose level greater than 126 mg/dL and HbA1c between 6.5 and 8 percent at least 3 months before the start of the study) Men or women in the age range is over 18 years with a body mass index of 18.5 to 30 kg/m2 . 3 Patients taking metformin Being able to communicate and volunteer to participate in the research. Signature written consent Residence in Isfahan city The possibility of continuous monitoring of patients.

Exclusion criteria:
Pregnancy and breastfeeding Smoking and alcohol consumption during study and in the last year Suffering from other underlying diseases such as severe liver failure, kidney failure (serum creatinine more than 4 mg/dL), severe cardiovascular diseases, stroke up to 3 months before the start of the research, cancer, inflammatory diseases, severe infection, and thyroid disorders. Taking drugs such as insulin, immunosuppressive drugs, anti-inflammatories. Taking medicinal supplements containing magnesium, thiamine or a history of allergy to these drugs. Patients with severe ketosis. Change in the type or dose of diabetes medication during the intervention. Patients with poor and inappropriate nutrition and with persistent anemia (hemoglobin less than 6 mg/dL). Patients who consume less than 90% of the tested medication will be excluded from the study Traveling for more than two weeks

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining a written consent and explaining how to conduct the research, the patients by using of rand function in Excel software divided into two groups (the patients and the treating physician and the person responsible for the statistical analysis do not know the type of drug), only one person who It directs people between two groups. It is aware of the study and replaces another person if one sample is removed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The doctor, the patient and the statistician do not know about the type of groupings and drugs

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jerib

City
Isfahan

Province
Isfehan

Postal code
91746-73461

Approval date
2023-10-02, 1402/07/10

Ethics committee reference number
IR.ARI.MUI.REC.1402.165

Health conditions studied

1

Description of health condition studied
Diabetes-Insulin resistance

ICD-10 code
E11.01

ICD-10 code description
Type 2 diabetes mellitus with hyperosmolarity with coma

Primary outcomes

1

Description
Fasting blood glucose-

Timepoint
Before intervention and every 3 months

Method of measurement
By using kit and according to the kit instructions

2

Description
HbA1c
Timepoint
Before intervention and every 3 months
Method of measurement
By using kit and according to the kit instructions

Secondary outcomes

1

Description
HOMA-IR
Timepoint
Before intervention and every three months
Method of measurement
By using specific kits

2

Description
GLUT4 gene expression
Timepoint
Before intervention and every three months
Method of measurement
By using specific kit

3

Description
FOXO1 gene expressions
Timepoint
Before intervention and every three months
Method of measurement
By using specific kit

Intervention groups

1

Description
Intervention group: Type 2 diabetic patients received metformin and capsule containing 300 mg magnesium sulphate and 100 mg thiamin
Category
Treatment - Drugs

2

Description
Control group: Type 2 diabetic patients received metformin and placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Siddiqa Kobari Hospital endocrine center affiliated to Isfahan University of Medical Sciences
Full name of responsible person
Mansoor Seyavash
Street address
Endocrine Research Center, Siddiqa Kobari Hospital, Khoram St
City
Isfahan
Province
Isfehan
Postal code
81876-98191
Phone
+98 31 3335 9933
Email
emrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Golamreza Askari
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3668 5149
Email
search@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Bijan Iraj
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
009837929001
Email
bijaniraj@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Nepton Soltani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Diabetes
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 9019
Email
neptun.soltani@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Nepton Soltani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Diabetes
Street address
Hezar Jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 9019
Email
neptun.soltani@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
After data analysis, the data will be presented as an article and a final report. Data will be made available to legal requesters after the information is de-identified
When the data will become available and for how long
After printing the articles and sending the final report to the vice president of research and technology of Isfahan University of Medical Sciences
To whom data/document is available
Vice President of Research and Technology of Isfahan University of Medical Sciences and Endocrine Research Center of Isfahan University of Medical Sciences
Under which criteria data/document could be used
Expanding the research or repeating the research by other endocrinologists
From where data/document is obtainable
Endocrine Research Center or Vice President of Research and Technology of Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
After receiving the request, correspondence will be made with the responsible executive, Vice President of Research and Technology and Endocrine Research Center of Isfahan University of Medical Sciences
Comments