

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)

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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

Isfahan

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

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Endocrine Research Center, Siddiqa Kobari Hospital, Khoram St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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Professor
Latest degree
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Person responsible for updating data

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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