Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Prevention effect of herbal mg supplement in insulin resistance in high fat patients

Protocol summary

Summary

The aim of this study is to determine the effect of herbal supplement containing 300 mg magnesium sulfate on lipid profile, insulin resistance and insulin secretion in overweight patients. Seventy six non-diabetic overweight volunteers with BMI >28 in kg/m2, general health in GI and cardiovascular system and non pregnant were included in a Randomized Double Blind Placebo-Controlled Clinical Trial, and received either placebo or a herbal supplement capsules containing 300 mg elemental magnesium (as magnesium sulfate -MgSO4-) daily, for 6 months. Metabolic control, lipid profile and magnesium status were determined at baseline and every three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110124756N2**
Registration date: **2015-11-26, 1394/09/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-26, 1394/09/05

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

Hormozgan University of Medical Science

Expected recruitment start date

1991-03-03, 1369/12/12

Expected recruitment end date

1993-01-01, 1371/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevention effect of herbal mg supplement in insulin resistance in high fat patients

Public title

Effect of magnesium on insulin resistance prevention

Purpose

Prevention

Inclusion/Exclusion criteria

BMI>28, general health in GI and cardiovascular system morbility, non diabetic, non pregnant, normotensive and no dietary restrictions or allergies, no history of food allergy or sensitivity to Mg supplements

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hormozgan University of Medical science
Street address
Emam Hossein Blv. Faculty of Medicine، Hormozgan University of Medical Science
City
Bandar Abbasa
Postal code
Approval date
2013-03-07, 1391/12/17
Ethics committee reference number
1394.57

Health conditions studied

1

Description of health condition studied
Insulin resistance
ICD-10 code
E66.9
ICD-10 code description
Obesity, unspecified

Primary outcomes

1

Description
Fasting Blood Sugar
Timepoint
Before intervention and every three months after intervention
Method of measurement
kit mg/dl

2

Description
Homa-IR
Timepoint
Before intervention and every three months after intervention
Method of measurement
HOMA–IR = FBG (mg/dl) × FPI (µu/ml) / 405)

Secondary outcomes

1

Description
Insulin
Timepoint
Before intervention and every three months after intervention
Method of measurement
Kit µu/ml

2

Description
Lipid profiles
Timepoint
Before intervention and every three months after intervention
Method of measurement
Kit mg/dl

Intervention groups

1

Description
Herbal MgSO4 For Mg-treated- group
Category
Prevention

2

Description
Placebo for control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Molecular Research center
Full name of responsible person
Nepton Soltani
Street address
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hormozgan University of Medical Science
Full name of responsible person
Dr Abdol Azim Nejatizadeh
Street address
Hormozgan University of Medical Science
City
Bandar abbas

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hormozgan University of Medical Science

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Hormozgan University of Medical Science
Full name of responsible person
Nepton Soltani
Position
PhD
Other areas of specialty/work
Street address
Hormozgan University of Medical Science
City
Bandar Abbas
Postal code
Phone
+98 76 3362 0876
Fax
Email
solnep2002@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hormozgan University of Medical Science
Full name of responsible person
Nepton Soltani
Position
PhD
Other areas of specialty/work
Street address
Hormozgan University of Medical Science
City
Bandar Abbas
Postal code
Phone
+98 76 3362 0876
Fax
Email
solnep2002@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hormozgan University of Medical Science
Full name of responsible person
Nepton Soltani
Position
PhD
Other areas of specialty/work
Street address
Faculty of Meicine
City
Bandar Abbas
Postal code
Phone
+98 76 3362 0876
Fax
+98 76 3333 7193
Email
solnep2002@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty