

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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 morbidity, 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 addressEmam 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

TimepointBefore intervention and every three months after
intervention**Method of measurement**

kit mg/dl

2**Description**

Homa-IR

TimepointBefore intervention and every three months after
intervention**Method of measurement** $\text{HOMA-IR} = \text{FBG (mg/dl)} \times \text{FPI (}\mu\text{u/ml)} / 405$ **Secondary outcomes****1****Description**

Insulin

TimepointBefore intervention and every three months after
intervention**Method of measurement**Kit $\mu\text{u/ml}$ **2****Description**

Lipid profiles

TimepointBefore 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**

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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*