

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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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.

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

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

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 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

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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