Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effect of vitamin D and/or magnesium supplementation on mood, serum level of BDNF, inflammation, and SIRT1 in obese women

Protocol summary

Study aim

Evaluation the effect of vitamin D and/or magnesium on mood, serum level of BDNF, inflammation, and SIRT1 in obese women

Design

The study will be done in Phase 3 clinical trials with a control group, in a factorial design, double-blind and randomized allocation. 80 eligible obese women will be randomly allocated into 4 groups (vitamin D, magnesium, cosupplementation, placebo). For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks.

Settings and conduct

Obese women, in Iran University of Medical Science, who meet the criteria, will be randomly allocated into 4 groups (vitamin D, magnesium, cosupplementation, placebo). Mood will be assessed using the Beck Depression Inventory at baseline and after week 8. Blood samples will be taken to quantify levels of 25(OH)D, inflammatory factors, and SIRT1 at baseline and after week 8. For blinding a person who will not be involved in protocol will create the randomization list. Tablets and placebo tablets will be placed into identical containers and will be randomly labeled. Investigators and participants will be blind to random assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI range of 30-40 kg/m2; Aged 18-50 years; 25(OH)D < 30 ng/ml; No renal, hepatic, and gastrointestinal disorders; Not taking vitamin D and magnesium or anti-depressant and anti-inflammatory drugs. Exclusion criteria: Unwillingness to participate in study

Intervention groups

Intervention 1: a 50000 IU vitamin D tablet, weekly+ a magnesium tablet (each tablet containing 250 mg magnesium in form of magnesium oxide), daily; Intervention 2: a 50000 IU vitamin D, weekly+a magnesium placebo, daily; Intervention 3: a magnesium tablet, daily+ a vitamin D placebo, weekly; Control: a vitamin D placebo, weekly+ a magnesium placebo.

Main outcome variables

Serum 25(OH)D; Serum TNF-α; level of IL-6; SIRT1; Serum BDNF; mood.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N23**
Registration date: **2019-08-16, 1398/05/25**
Registration timing: **prospective**

Last update: **2019-08-16, 1398/05/25**
Update count: **0**

Registration date

2019-08-16, 1398/05/25

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2020-11-05, 1399/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D and/or magnesium supplementation on mood, serum level of BDNF, inflammation, and SIRT1 in obese women

Public title

Effect of vitamin D & magnesium on inflammation and obesity- induced depressive symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese women with BMI range of 30-40 kg/m2 Aged 18-50 years Serum 25(OH)D < 30 ng/ml No autoimmune disease, renal, hepatic, parathyroid, and gastrointestinal disorders No taking vitamin D and/or magnesium supplements or anti-depressant and anti-inflammatory drugs

Exclusion criteria:

Affecting by any acute disease during the study Unwillingness to continue the study Less than 90% compliance with the treatment

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 80 subjects, 20 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug boxes that is generated by the software. Participants will be entered into study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, a person who will not be involved in study protocol will create the randomization list assigning participants to the vitamin D, magnesium, co-supplementation or the placebo group. Vitamin D, magnesium, and placebo tablets will be placed into identical containers which study manager will label them with participant numbers using the randomization list. All investigators, and participants will be blinded to the random assignments.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Institute for Medical Research Development (NIMAD)

Street address

National Institute for Medical Research Development, No 21, Besat St., West Fatemi St.

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Tehran

Province

Tehran

Postal code

1419693111

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.NIMAD.REC.1398.181

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Serum level of TNF-α.

Timepoint

Before and 8 weeks after intervention.

Method of measurement

Serum TNF-α levels will be assessed by ELISA and Bender Med kit (Bender Med, Germany).

Secondary outcomes

1

Description
Serum level of IL-6.
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Serum IL-6 levels will be assessed by ELISA and Bender Med kit (Bender Med, Germany).

2

Description
Serum level of BDNF.
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Serum BDNF levels will be assessed by ELISA and ZellBio kit (ZellBio, Germany).

3

Description
Serum level of SIRT-1.
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Serum SIRT-1 levels will be assessed by ELISA and ZellBio kit (ZellBio, Germany).

4

Description
Mood.
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Beck Depression Inventory.

Intervention groups

1

Description
Intervention group 1: a 50000 IU vitamin D tablet (Zahravi, Iran), weekly+ a magnesium tablet (each tablet containing 250 mg magnesium in the form of magnesium oxide) (Jalinous, Iran), daily, for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: a 50000 IU vitamin D tablet (Zahravi, Iran), weekly a magnesium placebo (Zahravi, Iran), daily, for 8 weeks.
Category
Treatment - Drugs

3

Description
Intervention group 3: a magnesium tablet (each tablet containing 250 mg magnesium in the form of magnesium oxide) (Jalinous, Iran), daily+ a vitamin D placebo (Zahravi, Iran), weekly, for 8 weeks.
Category
Treatment - Drugs

4

Description
Control group: a vitamin D placebo (Zahravi, Iran), weekly+ a magnesium placebo (Zahravi, Iran), daily, for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran University of Medical Science
Full name of responsible person
Dr. Seyed Kazem Malakouti
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Sponsors / Funding sources

1

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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
National Institute for Medical Research Development
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
Iran University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Vafa
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
A part of the data will be shared, such as primary

outcomes.

When the data will become available and for how long

Four months after the publication of the results.

To whom data/document is available

Researchers and students of university.

Under which criteria data/document could be used

Four months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

What processes are involved for a request to access data/document

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

Comments