Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of zinc and vitamin D separately and in combination on mood, cortisol, tryptophan—kynurenine pathway, BDNF and hs-CRP in overweight and obese subjects

Protocol summary

Summary

Objectives: To determine effects of zinc and vitamin D separately and in combination on mood, cortisol, tryptophan—kynurenine pathway, BDNF and hs-CRP in overweight and obese subjects. Design: Randomized double-blind placebo-controlled clinical trial. Participants: overweight and obese subjects. Setting and conduct: one hundred forty eligible overweight and obese subjects will be form Iran University of Medical Sciences personnel. Thy will be randomly assigned into four groups to receive daily 2000 IU vitamin D and 30 mg zinc, 2000 IU vitamin D and zinc placebo, 30 mg zinc and vitamin D placebo either zinc and vitamin D placebo for 12 weeks. Mood will be assessed at baseline and after weeks 12. 10 cc fasting venous blood samples will be obtained at the beginning and end of intervention and serum cortisol, tryptophan, kynurenine, BDNF and hs-CRP will be measured by ELISA. In order to control confounding factors, food intakes and physical activity will be assessed before and after intervention. Intervention: 2000 IU vitamin D and 30 mg zinc or placebo. Main outcome measures: mood, serum cortisol, tryptophan, kynurenine, BDNF and hs-CRP

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601252394N31**
Registration date: **2016-10-31, 1395/08/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name
Shima Jazayeri
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4805
Email address
sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research,Iran University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-05-01, 1396/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of zinc and vitamin D separately and in combination on mood, cortisol, tryptophan—kynurenine pathway, BDNF and hs-CRP in overweight and obese subjects

Public title

Effects of zinc and vitamin D separately and in combination on mood in overweight and obese subjects

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria:age between 20 to 60 years old; BMI > 27; willing to participate; weight stable in 3 last months. Exclusion criteria: Having a history of coronary artery disease; acute or chronic renal failure; acute or chronic hepatic failure; presence of any chronic inflammatory and autoimmune disease; and any known malignancy; hormone therapy; Other non-pathological exclusion criteria included pregnancy; breast feeding; post-menopause; smoking, professional athlete; uncontrolled thyroid disorder; use of medications for dyslipidemia or hypertension; having a special diet for any reason prescribed by the clinic dietitian; consumption of nutritional supplements within the past 8 weeks.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **140**
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
Ethic committee of Iran university of medical science
Street address
Iran University of Medical Sciences, Shahid Hemmet Highway, Tehran, Iran
City
Tehran
Postal code
Approval date
2016-06-12, 1395/03/23
Ethics committee reference number
IR.IUMS.REC 1395.9221324205

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66.9
ICD-10 code description
Simple obesity NOS

Primary outcomes

1

Description
Mood
Timepoint
At baseline and after weeks 12
Method of measurement
Beck Depression Inventory

2

Description
serum cortisol
Timepoint
At baseline and after weeks 12
Method of measurement
ELISA

3

Description
serum tryptophan
Timepoint
At baseline and after weeks 12
Method of measurement
ELISA

4

Description
serum kynurenine
Timepoint
At baseline and after weeks 12
Method of measurement
ELISA

5

Description
serum BDNF
Timepoint
At baseline and after weeks 12
Method of measurement
ELISA

Secondary outcomes

1

Description
serum hs-CRP
Timepoint

At baseline and after weeks 12

Method of measurement

ELISA

Intervention groups

1

Description

vitamin D- 2000 IU /day for 12 week zinc- 30 mg/day for 12 week

Category

Treatment - Other

2

Description

zinc Placebo- 30 mg/day for 12 week vitamin D Placebo- 2000 IU/day for 12 week

Category

Placebo

3

Description

vitamin D 2000 IU/day for 12 week and zinc placebo for 12 week

Category

Treatment - Drugs

4

Description

zinc 30 mg/day 12 week and vitamin D placebo for 12 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Science

Full name of responsible person

Somaye Yosaee

Street address

Tehran, Hemat Pathway, Iran University of Medical Science

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Iran University of Medical Science

Full name of responsible person

Dr. Seyed Ali Javad Moosavi

Street address

Iran University of Medical Sciences, Next to the Milad Hospital, Between the Intersection of Sheikh Fazlollah Noori and Chamran, Hemmat Highway

City

tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Iran 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

Department of Nutrition, School of public Health, Iran University of Medical Sciences

Full name of responsible person

Somaye Yosaee

Position

ph.D Candidate

Other areas of specialty/work

Street address

Iran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 8670 4805

Fax

Email

s_yousai2006@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Nutrition, School of public Health, Iran University of Medical Sciences

Full name of responsible person

Dr. Shima Jazayeri

Position

MD, PhD /Assistant Professor

Other areas of specialty/work

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran. Tehran
City
Tehran
Postal code
Phone
+98 21 8670 4805
Fax
Email
sh_jazayeri@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Somaye Yosaee
Position
ph.D candidate
Other areas of specialty/work
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Postal code
Phone
00
Fax
Email
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