

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of calorie restriction on blood pressure and plasma brain-derived neurotrophic factor in overweight or obese subjects

Protocol summary

Study aim

to compare effect of calorie restriction compared with no calorie restriction on blood pressure and plasma BDNF levels in overweight / obese patients undergoing stable treatment with antihypertensive drugs

Design

This is a parallel, non-blind, randomized clinical trial. In this study, participants who are eligible will be selected. Individuals are randomly assigned to one of two groups. The sequence of assigning individuals to the study groups is done using Random Allocation Software.

Settings and conduct

Overweight / obese people who regularly take high blood pressure medications are randomly assigned to one of two groups of low-calorie or regular non-calorie-restricted diets. The duration of the study will be 2 months. Patients with high blood pressure who are not calorie restricted are given general advice on daily consumption of vegetables, fruits and reducing salt intake. In both groups of calorie restriction, first the daily caloric requirement is calculated using the appropriate equation and coefficient of physical activity, and then about 500 calories are deducted from it, and the low-calorie diet using the substitution list method and the inclusion of all food groups is set.

Participants/Inclusion and exclusion criteria

Inclusion: • BMI>25 • age 40-70 • Regular use of antihypertensive drugs for at least the last 3 months • non-smoker • haven't been under any weight-loss diet at least 3 months before participating in the study
Exclusion: • Taking antipsychotic, anticonvulsant drugs • Cancer or chronic kidney disease stage 4-5 • Any changes in the disease treatment plan during the study, including changes in the type and dose of drugs used to affect blood pressure or surgery • Pregnancy or breastfeeding • Insulin treated patients • Taking omega 3 supplement

Intervention groups

-Low-calorie diet -Routine normal diet of the participants

Main outcome variables

Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160702028742N11**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **prospective**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

Javad Nasrollahzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0656

Email address

jnasrolah@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of calorie restriction on blood pressure and plasma brain-derived neurotrophic factor in overweight or obese subjects

Public title

Calorie restriction and plasma brain-derived neurotrophic factor

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with a body mass index higher than 25 Regular use of antihypertensive drugs for at least the last 3 months non-smoker Haven't been under any weight-loss diet at least 3 months before participating in the study

Exclusion criteria:

Taking antipsychotic, anticonvulsant drugs Cancer or stage 4 or 5 chronic or kidney disease Pregnancy or breastfeeding Any changes in the disease treatment plan during the study, including changes in the type and dose of drugs used to affect blood pressure or surgery• Insulin treated patients Taking omega 3 supplement

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of assigning individuals to the study groups is done using Random Allocation Software. The sequence will be placed in a sealed opaque envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethic committee of National Nutrition and Food

Technology Research Institute

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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Tehran

Province

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Postal code

1981619573

Approval date

2022-01-01, 1400/10/11

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1400.082

Health conditions studied**1****Description of health condition studied**

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Blood pressure

Timepoint

Baseline and the end of study

Method of measurement

Validated digital arm sphygmomanometer

Secondary outcomes**1****Description**

Plasma brain-derived neurotrophic factor

Timepoint

Baseline and the end of study

Method of measurement

ELISA

2**Description**

Plasma ICAM-1

Timepoint

Baseline and the end of study

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Low-calorie diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Clinic

Full name of responsible person

Mahsa Maeroofi

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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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

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Javad Nasrollahzadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available