

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of resveratrol on mood , cognitive function and serum BDNF in patients With type 2 diabetes

Protocol summary

Summary

Objectives: To determine effects of resveratrol on mood, cognitive function and serum BDNF in patients with type 2 diabetes. Design: Randomized double-blind placebo-controlled clinical trial. Participants: Patients with type 2 diabetes with a minimum score of 10 in Beck Depression Inventory. Setting and conduct: Sixty eligible patients with type 2 diabetes will be referred from Institute of Endocrinology and metabolism, Firoozgar Hospital. They will be randomly assigned into two groups to receive daily either 240 mg resveratrol or placebo for 8 weeks. Mood and cognitive performance will be assessed at baseline and after weeks 4 and 8. 10 cc fasting venous blood samples will be obtained at the beginning and end of intervention and serum BDNF will be measured by ELISA. In order to control confounding factors, height, weight, food intakes, physical activity, age, sex, FBS, HbA1c and medications will be assessed before and after intervention. Intervention: 240 mg resveratrol or placebo. Main outcome measures: mood, cognitive function, serum BDNF.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411112394N14**

Registration date: **2015-08-18, 1394/05/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-18, 1394/05/27

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of resveratrol on mood , cognitive function and serum BDNF in patients With type 2 diabetes

Public title

Effects of resveratrol on mood and cognition in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of type 2 Diabetes for at least 2 years; willing to participate; a minimum score of 10 in Beck Depression Inventory; age between 45 to 70 years old. Exclusion criteria: Significant diseases including cardiovascular, renal and liver diseases, or cancer; pregnancy; lactation; consumption of antidepressant agents within the past 8 weeks; insulin

use; consumption of nutritional supplements within the past 8 weeks.

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

14665-1579

Approval date

2014-06-17, 1393/03/27

Ethics committee reference number

93-03-27-25010

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Mood

Timepoint

At baseline and after weeks 4 and 8

Method of measurement

Beck Depression Inventory

2

Description

Cognitive performance

Timepoint

At baseline and after weeks 4 and 8

Method of measurement

Questionnaire

3

Description

Serum BDNF(brain-derived neurotrophic factor)

Timepoint

At baseline and after 8 weeks

Method of measurement

ELISA

Secondary outcomes

1

Description

HbA1c

Timepoint

At baseline and after 8 weeks

Method of measurement

Biochemical Assessment

2

Description

Fasting Blood Sugar

Timepoint

At the begining and end(week 8) of intervention

Method of measurement

Biochemical measurements

Intervention groups

1

Description

Resveratrol- 240 mg/day for 8 week

Category

Treatment - Other

2

Description

Placebo-240mg/day for 8 week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Institute of Endocrinology and Metabolism, Firouzgar Hospital, Iran University of Medical Sciences

Full name of responsible person

Dr. Iraj Heidari

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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 Science, Shahid 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

Fahime Ahmadi Motlaq

Position

Student of MSc Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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