

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The assesment of the effect of low calorie with moderate fiber diet on Brain-derived neurotrophic factor(BDNF) serum levels in obese and overweight type2 diabetic patients with different APO AII- 265T/C polymorphism

Protocol summary

Study aim

Determination of the effect of low energy diet with moderate fiber on the Brain-Driven Neurotrophic Factor (BDNF) in obese and overweight type 2 diabetic patients with different genotypes APO AII-265T / C

Design

A clinical trial study was performed on 56 diabetic patients with moderate-low-energy (moderate-diet) diet and after 6 weeks the serum BDNF level was measured.

Settings and conduct

Patients will receive a low-energy diet and moderate fiber for 6 weeks. Blood samples will be taken at the beginning and at the end of the study (after intervention), which will result in blood sampling of 15-20 ml and level The serum BDNF variable will be measured using commercial kits and by immuno-ELISA method. All phases of the study will be conducted in the laboratory of the Faculty of Health of Tehran University of Medical Sciences. Blind does not take place in this study.

Participants/Inclusion and exclusion criteria

Include criteria: Age range 45 to 65, BMI greater than or equal to 27, Type 2 diabetic patients who do not inject insulin Non-include criteria: drug use, cigar and other tobacco and alcohol, heart disease, stroke, liver disease, renal failure, thyroid disease, cancer, chronic inflammatory disease, pregnancy and lactation

Intervention groups

Obese and overweight type 2 diabetic patients with genotype CC and TT / TC of APOA2 gene

Main outcome variables

Brain-derived neurotrophic factor(BDNF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180715040479N1**

Registration date: **2018-10-02, 1397/07/10**

Registration timing: **retrospective**

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

Registration date

2018-10-02, 1397/07/10

Registrant information

Name

Ali Nazary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assesment of the effect of low calorie with moderate

fiber diet on Brain-derived neurotrophic factor(BDNF) serum levels in obese and overweight type2 diabetic patients with different APO AII- 265T/C polymorphism

Public title
The assesment of the effect of low calorie with moderate fiber diet on Brain-derived neurotrophic factor(BDNF) serum levels in obese and overweight type2 diabetic patients with different APO AII- 265T/C polymorphism

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
age range 45 to 65 years BMI over the 27 Patients with type 2 diabetes who do not inject insulin
Exclusion criteria:
Consumption drugs,tobacco,alcohol Heart disease, stroke, liver disease, kidney failure, thyroid disease, cancer, chronic inflammatory diseases consumption anti-inflammatory drugs and multi-vitamin minerals participate in other interventions Pregnancy and lactation

Age
From **45 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Qods Ave, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-06-28, 1397/04/07

Ethics committee reference number

IR.TUMS.VCR.REC.1397.168

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Brain-derived neurotrophic factor (BDNF)

Timepoint

The beginning of the study (before the intervention) and the end of the study (after the intervention)

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Obesity and Overweight

Timepoint

The beginning of the study (before the intervention) and the end of the study (after intervention)

Method of measurement

Scales

Intervention groups

1

Description

Intervention group: This study will be performed on 56 diabetic patients. Patients will have a low-energy and fiber-rich diet (30 g / day) containing 55-65% carbohydrates, 20-25% fat and 15-20% % Protein will be received. After calculating the amount of energy required, the dietary regimen is adjusted daily for each individual. A total of 21 menu items are set with specific energy, and in each week, 7 calorie-like diets are given to people who have the power to select the desired menu and even repeat it per week. Also, the share of energy in each and every one is the same, which allows people to choose between their meals, such as breakfast, their favorite menu. At the beginning and at the end of the study (after intervention), blood samples

are collected from patients, thus collecting 15-20 ml of blood.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of School of Public Health

Full name of responsible person

Fariba Koohdani

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School of Public Health, Poorsina Ave, Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fariba koohdani

Position

professor of cellular and molecular nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Nazary

Position

Student of Nutrition Science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

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

Title and more details about the data/document

All laboratory data of individuals including blood factors, glucose and fat and other measurable factors in the study will be shared.

When the data will become available and for how long

Access to data will be possible for the second half of 1398

To whom data/document is available

Researchers working in academic and academic institutions

Under which criteria data/document could be used

Statistical analysis related to Trail's studies Use this data solely to conduct a new research Use data to write systematic review articles and meta-analyzes

From where data/document is obtainable

Dr Fariba koohdani- fkoohdan@tums.ac.ir Dr Maasumeh moradi 00989128390869

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

All results and documentation will be available up to 1 year after the completion of sampling

Comments