

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

clinical trial of calorie restriction with medium fiber diet on serum levels of some inflammatory factors and their gene expression in obese and overweight type 2 diabetic patients with CC and TT/TC polymorphism in APOA-II and comparison of changes in these genotypes

Protocol summary

Summary

In this study for the first time we evaluate the effects of dietary energy reduction and increase fiber intake to individuals with polymorphisms T-C 256- APOAII. This study is a non-randomized, not blinded and without placebo that is done on 56 patients with type II diabetes. Diabetic samples will elect from 800 samples which has been collected in the previous study and took in two groups of CC genotype and T allele carrier group includes TT or TC. Of these, 28 patients with CC genotype are selected. Inclusion criteria are an age range between 45 to 65 years, BMI greater than or equal to 27 and any injection of insulin. Exclusion criteria consist of use of tobacco and alcohol, patients with chronic inflammatory diseases and use of Anti-inflammatory medications or multivitamin and mineral supplements. The t allele carrier group will be homologized in terms of gender, receiving lipid-lowering drugs, BMI and age with CC group. Patients will receive low-energy diet(500-1000 calorie less than their needs), rich in fiber (30 grams per day) during 6 weeks. Blood samples will be taken before the study and at the end of the intervention and the levels of certain serum factors such as TNF- α , NFkB, ICAM1, VCAM1 and HDL2 and HDL3 and enzyme LCAT, PON1, PON3 and their relationship with APOA-I and APOA-II we will study. The gene expression of PTX3, VCAM1, ICAM1 will be measured.

General information

Acronym

apoa2=apolipoprotein a2

IRCT registration information

IRCT registration number: **IRCT2015071323195N1**

Registration date: **2015-10-22, 1394/07/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

Name

Masoumeh Moradi

Name of organization / entity

Tehran University of Medical Sciences, School of Nutritional Science and Dietetics

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5568

Email address

m_moradi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences International Campus

Expected recruitment start date

2015-10-12, 1394/07/20

Expected recruitment end date

2016-01-10, 1394/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical trial of calorie restriction with medium fiber diet on serum levels of some inflammatory factors and their gene expression in obese and overweight type 2 diabetic

patients with CC and TT/TC polymorphism in APOA-II and comparison of changes in these genotypes

Public title

the effect of calorie restriction with medium fiber diet in obese and overweight type 2 diabetic patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: age between 45-65 years; BMI more than or equal 27; type 2 diabetes who do not inject insulin Exclusion criteria: compliance of dietary recommendations less than 80%; Acute inflammatory diseases in the last 3 days before blood sampling; receiving antiinflammatory medications and multivitamin mineral supplements during the intervention

Age

From **49 years** old to **29 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

N/A

Randomization description

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

Ethics committee of Tehran University of Medical Sciences

Street address

Poorsina Avenue, Ghods Street, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2015-09-21, 1394/06/30

Ethics committee reference number

IR.TUMS.REC.1394.805

Health conditions studied

1

Description of health condition studied

non-insulin-dependent diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

2

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Obesity

Primary outcomes

1

Description

paraoxonase 1 enzyme

Timepoint

before and after intervention

Method of measurement

kit

2

Description

activity of LCAT enzyme

Timepoint

before and after intervention

Method of measurement

kit

3

Description

serum TNF- α

Timepoint

before and after intervention

Method of measurement

kit

4

Description

VCAM1, ICAM1, PTX3 gene expression

Timepoint

before and after intervention

Method of measurement

Real-Time PCR

5

Description

paraoxonase3 enzyme

Timepoint

before and after intervention
Method of measurement
kit

6

Description

serum NFKB

Timepoint

before and after intervention

Method of measurement

kit

7

Description

serum ICAM1

Timepoint

before and after intervention

Method of measurement

kit

8

Description

serum VCAM1

Timepoint

before and after intervention

Method of measurement

kit

9

Description

serum HDL2 and HDL3

Timepoint

before and after intervention

Method of measurement

kit

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

During a 6-week patients will receive low-energy diet and moderate fiber (30 grams per day) including 55 to 65% carbohydrates, 20% protein and 25% fat. To get enough fiber in addition to increasing the consumption of fruits and vegetables will add wheat bran to the diet and to ensure the same type of bran consumption the required

amount will be available to them every two weeks. After calculating the amount of energy needed for daily, diets will be set for each individual. 21 food menu with identified calorie will prepare for each person and every two weeks we will give them 7 menu with same calorie to the individuals which give them the power to choose the desired menu and even have a repeat in the week. And they also share the same energy that allows people to use between meals, such as breakfast menu to choose their favorite

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University School of Public Health Laboratories

Full name of responsible person

Mr. Ehsan Alvandi

Street address

Poorsina Avenue, Ghods Street, Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences International
Campus, School of Nutritional Science and Dietetics

Full name of responsible person

Mrs. Dr. Fariba Kuhdani

Street address

Number 44, Hojatdoost Avenue, Naderi Street,
Keshavarz Blvd.

City

Tehran

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 International
Campus, School of Nutritional Science and Dietetics

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

Tehran University of Medical Sciences, School of
Nutritional Science and Dietetics

Full name of responsible person

Masoumeh Moradi

Position

ph.D student

Other areas of specialty/work**Street address**

Number 44, Hojatdust Avenue, Naderi Street,
Keshavarz Blvd

City

Tehran

Postal code**Phone**

+98 21 4473 3292

Fax**Email**

moradi_ma@yahoo.com;m_moradi@razi.tums.ac.ir

Web page address

+98 21 8895 5569

Fax**Email**

fkoohdan@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences, School of
Nutritional Science and Dietetics

Full name of responsible person

Masoumeh Moradi

Position

ph.D student of nutrition

Other areas of specialty/work**Street address**

Number 44, Hojatdoost Avenue, Naderi Street,
Keshavarz Blvd.

City

Tehran

Postal code**Phone**

+98 44733292

Fax**Email**

moradi_ma@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, School of
Nutritional Science and Dietetics

Full name of responsible person

Dr. Fariba Koohdani

Position

research assistant

Other areas of specialty/work**Street address**

Number 44, Hojatdust avenue, Naderi Street,
Keshavarz Blvd

City

Tehran

Postal code**Phone**

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