

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of low calorie diet on plasma levels of miR-33b, -375, -935 and -29a, state of insulin resistance and lipid metabolism in obese women with type II diabetes

Protocol summary

Summary

This study will be explored the effects of low-calorie diet on plasma levels of MIRs -33b -, 375 -, 935 and a 29 -in relation to insulin resistance, glucose and lipid metabolism in obese women with type II diabetes. In this randomiZed clinical trial, totally 20 obese women ($BMI \leq 45 \geq 30 \text{ kg/m}^2$) at the age range of 25 to 60y, with at lest 2 years diagnosis of T2DM, without history of insulin treatment, any especial diet in 6last month, liver, kidney and other metabolic diseases were recruited from the out patients clinic of Emdady hospital. Patients will be divided in two groups with randomized blocking method, low calorie diet and control groups. The 8-week low-calorie diet will be based on the exchange list (the value obtained by subtracting 700 calories from a standard formula with calculating the coefficient of outdoor activities). At the beginning and end of the study questionnaires, including demographic, 3-day food recall, validated food frequency questionnaire will be completed. Laboratory and anthropometric measurements measurements including FBS, OGTT, serum insulin, glucagon, adiponectin, TNF- α and lipid profile, height, weight, BMI, waist and hip circumference and WHR will be performed for all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011416223N1**

Registration date: **2014-01-23, 1392/11/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-23, 1392/11/03

Registrant information

Name

Somayeh Mohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41133575803

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mohammadis.phd@gmail.com

Recruitment status

Recruitment complete

Funding source

Tabriz University of medical Sciences, Shahid beheshti University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low calorie diet on plasma levels of miR-33b, -375, -935 and -29a, state of insulin resistance and lipid metabolism in obese women with type II diabetes

Public title

The effect of diet therapy as epigenetic factors in the control of diabetic complications

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: Women with type 2 diabetes diagnosed at least two years by specialist; The age range of 25 to 60; The degree of obesity in accordance with the definition of a BMI $\leq 45 \text{ kg/m}^2 \geq 30$; Willingness to participate in research. The exclusion criteria: Patients who did not complete the questionnaire; Unwillingness to blood sampling; BMI over 45; Following a special diet like vegetarian diet, low calorie diet or weight-loss medications for obesity last year; More than three kilograms of weight change over the past six months; Pregnancy, lactation, menstruation irregular; Chronic cigarette smokers (3 days more than 48 months) or alcohol; Vitamin and mineral supplements; protein and phytoestrogens period of 3 months prior to study entry; Taking hormonal contraceptives, anticonvulsants, glucocorticoids during the recent 3 months; Patients with type 1 diabetes mellitus; Kidney disease, liver disease, hyperthyroidism, a chronic inflammation (such as rheumatoid arthritis, multiple sclerosis, rash, etc.) and a variety of benign and malignant masses.

Age

From **25 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Research vice-chancellors, Golgasht st, Azadi ave, Tabriz, Iran

City

Tabriz

Postal code

5166614711

Approval date

2013-12-16, 1392/09/25

Ethics committee reference number

5/4/8407

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

micro RNA-29a

Timepoint

before and 2 month after intervention

Method of measurement

qRT-PCR, copy number of micro RNAs per each micro liter of plasma and deffrent percent with interior standard

2

Description

micro rna-375

Timepoint

before and 2 month after intervention

Method of measurement

qRT-PCR, copy number of micro RNAs per each micro liter of plasma and deffrent percent with interior standard

3

Description

micro RNA-33b

Timepoint

before and 2 month after intervention

Method of measurement

qRT-PCR, copy number of micro RNAs per each micro liter of plasma and deffrent percent with interior standard

4

Description

micro RNA-935

Timepoint

before and 2 month after intervention

Method of measurement

qRT-PCR, copy number of micro RNAs/ micro liter of plasma and deffrent percent with interior standard

5

Description

Fasting serum insulin concentration

Timepoint

before and 2 month after intervention
Method of measurement
ELISA, µU/mL

6

Description
Plasma insulin concentration 2 hours after meal
Timepoint
before and 2 month after intervention
Method of measurement
ELISA, µU/mL

7

Description
Serum adiponectin levels
Timepoint
before and 2 month after intervention
Method of measurement
ELISA, ng/dL

8

Description
Serum TNF-α levels
Timepoint
before and 2 month after intervention
Method of measurement
ELISA, ng/dL

9

Description
Fasting blood glucose
Timepoint
before and 2 month after intervention
Method of measurement
enzymatic colorimetric assay, mg/dL

10

Description
Blood glucose, blood glucose 2 hours after meal
Timepoint
before and 2 month after intervention
Method of measurement
enzymatic colorimetric assay, mg/dL

11

Description
Serum total cholesterol
Timepoint
before and 2 month after intervention
Method of measurement
enzymatic colorimetric assay, mg/dL

12

Description
Serum LDL-C
Timepoint
before and 2 month after intervention

Method of measurement
enzymatic colorimetric assay, mg/dL

13

Description
Serum HDL-C
Timepoint
before and 2 month after intervention
Method of measurement
enzymatic colorimetric assay, mg/dL

14

Description
Serum triglyceride level
Timepoint
before and 2 month after intervention
Method of measurement
enzymatic colorimetric assay, mg/dL

15

Description
Weight
Timepoint
before, 1 and 2 month after intervention
Method of measurement
Scale of body analyzer, Kg

16

Description
BMI
Timepoint
before, 1 and 2 month after intervention
Method of measurement
Calculating by equation, Kg/m²

17

Description
Waist circumference
Timepoint
before, 1 and 2 month after intervention
Method of measurement
Tape, Centimeter

18

Description
Hip circumference
Timepoint
before, 1 and 2 month after intervention
Method of measurement
Tape, Centimeter

19

Description
Waist to hip ratio
Timepoint
before, 1 and 2 month after intervention
Method of measurement

Calculating by equation, cm/cm

20

Description

Waist to height ratio

Timepoint

before, 1 and 2 month after intervention

Method of measurement

Calculating by equation, m/m

21

Description

HOMA-IR

Timepoint

before and 2 month after intervention

Method of measurement

HOMA-IR equation

22

Description

QUICKI

Timepoint

before, 1 and 2 month after intervention

Method of measurement

QUICKI equation

Secondary outcomes

1

Description

Calorie intake

Timepoint

Before, 1 month and 2 month after intervention

Method of measurement

3 day food recall and Food frequency questionnaire,
Kcal/day

2

Description

Carbohydrate intake

Timepoint

Before, 1 month and 2 month after intervention

Method of measurement

3 day food recall and Food frequency questionnaire,
g/day

3

Description

Protein intake

Timepoint

Before, 1 month and 2 month after intervention

Method of measurement

3 day food recall and Food frequency questionnaire,
g/day

4

Description

Fat intake

Timepoint

Before, 1 month and 2 month after intervention

Method of measurement

3 day food recall and Food frequency
questionnaire,g/day

Intervention groups

1

Description

Intervention group: A 8-week low calorie diet)based on subtracting 700 calories from standard formula to predict energy expenditure estimated at four levels of physical activity for obese women 19 years old and above(and planning individual diet based on exchange list.

Category

Treatment - Other

2

Description

Control group: without low calorie diet- Continuing with their common diet for 8-week

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdadi hospital

Full name of responsible person

Somayeh Mohammadi

Street address

Diabetes clinic, Emdadi Hospitals, Transite street,
Zanjan University of Medical Sciences, Abhar, Zanjan

City

Abhar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Vice-Chancellor's Office in Research Affairs,
Dr.Mohammad Reza Rashidi

Street address

Azadi street, Golgasht avenue, ,Tabriz, Iran

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice-Chancellor's Office in Research Affairs- Dr.Afshin Zarghi

Street address

Velenjak St. , Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences, Tehran, Iran

City

Tehran

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

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

Tabriz University of Medical Sciences

Full name of responsible person

Somayeh Mohammadi

Position

Ph.D candidate in nutrition sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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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