

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of a low calorie diet on metabolic status in normal and overweight patients with type 2 diabetes

Protocol summary

Study aim

The effect of a low calorie diet on metabolic status in normal and overweight patients with type 2 diabetes

Design

In this study, 120 patients with type 2 diabetes (60 patients with normal weight and 60 patients with overweight) who were admitted to study at the endocrine clinic of Imam Khomeini Hospital in Urmia were selected.

Settings and conduct

This study will be conducted at Urmia University of Medical Sciences for 12 weeks. In this study, low calorie diet (reduction of 500 kc a day) will be given to intervention groups.

Participants/Inclusion and exclusion criteria

Criteria for inclusion in the study: normal and overweight patients with type 2 diabetes; Aged between 18 to 65; Consumption of same drugs (glibenclamide, metformin).
Criteria for exclusion from the study: Suffering from liver diseases; Suffering from thyroid disease; Pregnancy and lactation; Smoking and drinking alcohol; Consumption of drugs reducing blood fat and pressure and Weight, thiazide diuretics and corticosteroids; Change of type and dosage of consuming drugs during the study; Consumption of Herbal or chemical supplements; Suffering from Digestive diseases associated with malabsorption; Gastric bypass surgery and cholecystectomy; Insulin Therapy; people who have been on weight loss diet or had been treated with drugs and supplements related to weight loss (such as Orlistat or Slim Last dietary supplements) in the past three months; Suffering from diabetic complications such as nephropathy, retinopathy, neuropathy and cardiovascular complications;

Intervention groups

Normal weight diabetes patients are randomly divided into two intervention (n=30) and control (n=30) groups and overweight diabetes patients are randomly divided into two intervention (n=30) and control (n=30) groups.

Main outcome variables

Glycemic index, Lipid profile, Liver enzymes, body composition and blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170214032571N10**

Registration date: **2019-07-28, 1398/05/06**

Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**

Update count: **0**

Registration date

2019-07-28, 1398/05/06

Registrant information

Name

Majid Manafi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 32770698

Email address

manafi.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a low calorie diet on metabolic status in normal and overweight patients with type 2 diabetes

Public title

The effect of a low calorie diet in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Criteria for inclusion in the study: normal and overweight patients with type 2 diabetes Aged between 18 to 65 Consumption of same drugs (glibenclamide, metformin)

Exclusion criteria:

Criteria for exclusion from the study: Suffering from liver diseases Suffering from thyroid disease Pregnancy and lactation Smoking and drinking alcohol Consumption of drugs reducing blood fat and pressure and Weight, thiazide diuretics and corticosteroids Change of type and dosage of consuming drugs during the study Consumption of Herbal or chemical supplements Suffering from Digestive diseases associated with malabsorption Gastric bypass surgery and cholecystectomy Insulin Therapy people who have been on weight loss diet or had been treated with drugs and supplements related to weight loss (such as Orlistat or Slim Last dietary supplements) in the past three months Suffering from diabetic complications such as nephropathy, retinopathy, neuropathy and cardiovascular complications

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

The volunteers were randomly assigned to intervention and control groups with normal weight and overweight, and stratified block randomization was performed based on age and sex.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

During the study, patients have a constant physical

activity.

Secondary Ids

empty

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

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, orjans valley, Rresalat boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5715799313

Approval date

2018-04-17, 1397/01/28

Ethics committee reference number

IR.UMSU.REC.1397.034

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

Type 2 diabetes

ICD-10 code

Diabetes m

ICD-10 code description

E11

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

Insulin resistance

Timepoint

At weeks 0, 12

Method of measurement

$$(fasting\ serum\ glucose\ (mmol/L) \times fasting\ serum\ insulin\ (\mu U/ml))/22.5$$
2**Description**

Quantitative Insulin Sensitivity Check Index

Timepoint

At weeks 0, 12

Method of measurement

$$1/ [\log(fasting\ insulin, \mu U/ml) + \log (fasting\ glucose, mg/dl)]$$

3

Description

Fasting Blood Sugar

Timepoint

At weeks 0, 12

Method of measurement

Enzymatic method, mg/dl

4

Description

Serum insulin

Timepoint

At weeks 0, 12

Method of measurement

Radioimmunoassay

5

Description

Systolic blood pressure

Timepoint

At weeks 0, 12

Method of measurement

Mercury pressure gauge, Mm mercury

6

Description

Diastolic blood pressure

Timepoint

At weeks 0, 12

Method of measurement

Mercury pressure gauge, Mm mercury

7

Description

Body composition analysis (Weight, Body mass index, Fat mass, Fat free mass, Visceral fat area, Waist circle, Waist to hip ratio, Skeletal muscle mass)

Timepoint

At weeks 0, 12

Method of measurement

Inbody770 Body Analyzer, Bioelectrical impedance analysis

8

Description

HbA1c

Timepoint

At weeks 0, 12

Method of measurement

Enzymatic method, %

9

Description

Lipid profile (Triglyceride, Total cholesterol, VLDL, LDL, HDL)

Timepoint

At weeks 0, 12

Method of measurement

Enzymatic method, mg / dl

10

Description

Liver enzymes (ALP, ALT, AST)

Timepoint

At weeks 0, 12

Method of measurement

Enzymatic method, IU/L

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A = Intervention in normal weight diabetes patients by reducing 500kcal of daily energy requirement for 12 months

Category

Prevention

2

Description

Intervention group: Group B = Intervention in overweight diabetes patients by reducing 500kcal of daily energy requirement for 12 months

Category

Prevention

3

Description

Control group: Group C = Normal weight diabetes patients without reducing 500kcal of daily energy requirement for 12 months

Category

Other

4

Description

Control group: Group D = Overweight diabetes patients without reducing 500kcal of daily energy requirement for 12 months

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital of Urmia

Full name of responsible person

Dr. Alireza Mehdizade

Street address

Floor 2, Imam Khomeini Hospital professional clinic
(1), Ershad Ave

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+98 76 0132 2344

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majidmanafi@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebi

Street address

Orjhans street, Resalat Blvd, Urmia

City

Urmia

Province

West Azarbaijan

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5714783734

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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

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Majid Monafi

Position

Master of Science in Nutritional Science/ Faculty
Member

Latest degree

Master

Other areas of specialty/work

Nutrition

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Other areas of specialty/work

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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