

# 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

**Age**

From **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**

$(\text{fasting serum glucose (mmol/L)} \times \text{fasting serum insulin } (\mu\text{U/ml}))/22.5$

**2****Description**

Quantitative Insulin Sensitivity Check Index

**Timepoint**

At weeks 0, 12

**Method of measurement**

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

### 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

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715799313

**Phone**

+98 76 0132 2344

**Email**

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

**Postal code**

5714783734

**Phone**

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majidmanafi@yahoo.com

**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

**Street address**

Nutrition Department, Faculty of Medicine, College of  
Medicine, Urmia University of Medical Science, 11th  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Majid Monafi

**Position**

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

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**Full name of responsible person**

Majid Manafi

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**Province**

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majidmanafi@yahoo.com

**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