

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of ginger (*zingiber officinale*) on glucose, HbA1c and insulin sensitivity in type 2 diabetic patients

#### Protocol summary

##### Summary

This study is a randomized double-blind placebo controlled trial that will carry on 60 diabetic patients according to specialist diagnosis from clinics of Tabriz University of Medical Science. The aim of the study is to evaluate the effect of zingiber officinal supplementation on some blood biochemical parameters in type 2 Diabetes Mellitus patients. Patients will be divided randomly to 2 groups; intervention group : patients receive 2 pill containing 1g powder of ginger herb, and placebo group patients take 2 pill containing 1g isomalt for 60 days. Anthropometric measurements (weight, height), biochemical criteria including lipid profile (TG,TC,HDL-C,LDL-C), blood glucose, HbA1c and insulin using 5cc blood collected, physical activity levels and dietary record will be measured before and after treatment (8 week).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202232017N7**

Registration date: **2012-04-17, 1391/01/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-04-17, 1391/01/29

##### Registrant information

##### Name

Alireza Ostadrahimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

ostadrahimi@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research, Tabriz University Of Medical Sciences

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2012-06-21, 1391/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of ginger (*zingiber officinale*) on glucose, HbA1c and insulin sensitivity in type 2 diabetic patients

##### Public title

The effect of ginger (*zingiber officinale*) on glucose, HbA1c and insulin sensitivity in type 2 diabetic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age between 18-65 years; proven diagnosis for diabetes mellitus by experts; absence of antioxidants supplementation in previous months or in the study and absence of special diet. Exclusion criteria: history of impaired immune system; alcohol use and depression, nephrotic syndrome, peptic ulcer, gastrointestinal disorders, Pregnancy and Lactation, Consumption of alcoholic beverages, food allergies.

##### 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: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Tabriz University of Medical Sciences Ethics Committee

**Street address**

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz, East Azarbayjan ,Iran

**City**

Tabriz

**Postal code**

**Approval date**

2012-03-12, 1390/12/22

**Ethics committee reference number**

9090

**Health conditions studied**

1

**Description of health condition studied**

type 2 diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

**Primary outcomes**

1

**Description**

Glucose and HbA1c

**Timepoint**

Before and after intervention

**Method of measurement**

Enzymatic method and ELISA method for HbA1c

**Secondary outcomes**

1

**Description**

Insulin sensitivity

**Timepoint**

Before and after intervention

**Method of measurement**

Insulin measured by ELISA

2

**Description**

Lipid profile

**Timepoint**

Before and after the intervention

**Method of measurement**

Enzymatic method for total cholesterol and HDL and Freidwald's formula for LDL

**Intervention groups**

1

**Description**

Intervention group:2 pill containing 1g powder of ginger for 60 day

**Category**

Treatment - Drugs

2

**Description**

Placebo group: 2 pill containing 1g powder of isomalt for 60 day

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

The clinics of Tabriz University Of Medical Sciences

**Full name of responsible person**

sepide mahluji

**Street address**

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz , East Azarbayjan ,Iran, Islamic Republic Of east azarbayjan

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for research-Tabriz University of Medical Science

**Full name of responsible person**

Mohammad Reza Rashidi

**Street address**

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz , East Azarbayjan ,Iran

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for research-Tabriz University of Medical Science

**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**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Sepide Mahluji

**Position**

MSc student in Nutrition

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

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz East Azarbayjan Iran,

**City**

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**Postal code****Phone**

+98 41 1335 2295

**Fax****Email**

s\_mahluji@yahoo.com

**Web page address**

## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Alireza Ostadrahimi

**Position**

Associate professor in Nutrition

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

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## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Sepide Mahluji

**Position**

MSc student in Nutrition

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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*