# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jun 2026

# The effect of ginger on glycemic status, apolipoprotein B, apolipoprotein A-I, total antioxidant capacity (TAC), malondialdehyde (MDA), high sensitivity c-reactive protein (hsCRP), and paraoxonase in type 2 diabetic patients

## Protocol summary

**Summary**
This study examined The effect of ginger on glycemic status, apolipoprotein B, apolipoprotein A-I, total antioxidant capacity (TAC), malondialdehyde (MDA), high sensitivity c-reactive protein (hsCRP), and paraoxonase in type 2 diabetic patians.In this placebo-controlled double-blind randomized clinical trial, 70 patients with diabetes who qualify and are enrolled into the study.Patients in case group are receiving about 3 grams of powdered ginger daily for 3 months and control patients are receiving 3 glactose powder daily for 3 months.After the 3-month intervention period, glycemic status, apolipoprotein B, apolipoprotein A-I, total antioxidant capacity (TAC), malondialdehyde (MDA), high sensitivity c-reactive protein (hsCRP), and paraoxonase 2 groups will be compared.

## General information

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT201109082709N19**
Registration date: **2011-10-07, 1390/07/15**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**
2011-10-07, 1390/07/15

**Registrant information**
**Name**
Farzad Shidfar
**Name of organization / entity**
Iran University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**
Vice-chancellor for Research, Tehran University of Medical Sciences

**Expected recruitment start date**
2011-10-23, 1390/08/01
**Expected recruitment end date**
2012-02-19, 1390/11/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of ginger on glycemic status, apolipoprotein B, apolipoprotein A-I, total antioxidant capacity (TAC), malondialdehyde (MDA), high sensitivity c-reactive protein (hsCRP), and paraoxonase in type 2 diabetic patients

**Public title**
The effect of ginger on glycemic status, apolipoprotein B, apolipoprotein A-I, total antioxidant capacity (TAC), malondialdehyde (MDA), high sensitivity c-reactive protein (hsCRP), and paraoxonase in type 2 diabetic patiants
**Purpose**
Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria:Non-insulin dependent diabetic patients with type 2 diabetes that is diagnosed by a physician, Endocrinologist.Diabetes duration of at least 2 years , 20-60 ages,Hb A1c :6-8% , Lack of antioxidant supplements such as selenium, zinc, beta carotene, and ... At least 3 months before the study - not smoking, and alcohol - a willingness to cooperate with exclusion criteria: Patient unwillingness to continue with the plan - changes in type or dose of medication, Changes in diet or physical activity every day - taking any antioxidant supplements - taking less than 80% of supplements given to patients at baseline(the compaliance lower than %80),Recent receive insulin - pregnancy and lactation - renal , hepatic , thyroid diseases and anemia - hypersensitivity to the drug

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**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**

Vive-chancellor for Research, Tehran University of Medical Sciences

**Street address**

Keshavarz Bld - intersection of Qods street

**City**

Tehran

**Postal code**

**Approval date**

2011-07-12, 1390/04/21

**Ethics committee reference number**

132/1287

## Health conditions studied

### 1

**Description of health condition studied**

type 2 diabetese melitus

**ICD-10 code**

E11

**ICD-10 code description**

R81

## Primary outcomes

### 1

**Description**

fasting blood sugar

**Timepoint**

before & after intervention (3 months later)

**Method of measurement**

glucose oxidase method

### 2

**Description**

Hb A1C

**Timepoint**

before & after intervention (3 months later)

**Method of measurement**

colorimetry

### 3

**Description**

insulin

**Timepoint**

before & after intervention (3 months later)

**Method of measurement**

IRMA

### 4

**Description**

insulin resistance

**Timepoint**

before & after intervention (3 months later)

**Method of measurement**

insulin × glucose / 22.5

### 5

**Description**

Apo A

**Timepoint**

before & after intervention (3 months later)

**Method of measurement**

immunotorbidometry

### 6

**Description**

Apo B

**Timepoint**

before & after intervention (3 months later)
**Method of measurement**
immunotorbidometry

**7**

**Description**
Apo B/Apo A-I
**Timepoint**
before & after intervention (3 months later)
**Method of measurement**
ratio

**8**

**Description**
high-sensitivity C-Reactive Protein
**Timepoint**
before & after intervention (3 months later)
**Method of measurement**
ELISA kitt

**9**

**Description**
total antioxidant capacity
**Timepoint**
before & after intervention (3 months later)
**Method of measurement**
colorimetry (FRAP)

**10**

**Description**
malondealdehyde
**Timepoint**
before & after intervention (3 months later)
**Method of measurement**
colorimetry

**11**

**Description**
paraoxonase
**Timepoint**
before & after intervention (3 months later)
**Method of measurement**
colorimetry

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
intervention group : ginger supplement, 3 gram per day and during 3 months
**Category**
Treatment - Drugs

**2**

**Description**
control group : lactose supplement, 2 grams per day and during 3 months
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Iran Diabetes Association
**Full name of responsible person**
Dr Asaddollah Rajab
**Street address**
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vive-chancellor for Research, Tehran University of Medical Sciences
**Full name of responsible person**
Dr Seyyed Abbas Motevalian
**Street address**
Keshavarz Bld - intersection of Qods street
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vive-chancellor for Research, Tehran University of Medical Sciences
**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**
School of Public Health of Tehran University of Medical Sciences
**Full name of responsible person**

Dr Farzad Shidfar

**Position**

Professor Assistant/nutrition PhD

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Full name of responsible person**

Dr Farzad Shidfar

**Position**

Professor Assistant/nutrition PhD

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

## 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*