Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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

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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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School of Public Health of Tehran University of Medical Sciences

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Web page address

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