

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effects of ginger on insulin resistance, lipid profile & lipoproteins in patients with type 2 diabetes

Protocol summary

Summary

This investigation is a randomized controlled clinical trial to determine the effect of ginger on insulin resistance, lipid profiles and lipoproteins in patients with type 2 diabetes. The sample size of study is 84 cases. Inclusion criteria: patients with type 2 diabetes, patients newly diagnosed diabetes to 10 years, no pregnancy and lactation, lack of vitamin and mineral supplementation, without any thyroid, kidney, CVD diseases and not using TG & cholesterol lowering drugs, and also using ESTROGEN or PROGESTRON, FBS<180, 2Hpp<250. Exclusion criteria: using insulin. They are randomly selected. They are assigned to two groups based on random numbers table. Patients receive capsules ginger or placebo 3 times a day, 1 gram for 2 months. FBS, fasting insulin, cholesterol, triglyceride, LDL and HDL cholesterol and APO-A1, APO-B100, insulin resistance and sensitivity to insulin are measured before and after the time of the follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104246278N1**

Registration date: **2011-06-03, 1390/03/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-03, 1390/03/13

Registrant information

Name

Behrouz Talaei

Name of organization / entity

Yazd University of Medical Sciences and Health

Services

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences and Health Services

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-06-21, 1390/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of ginger on insulin resistance, lipid profile & lipoproteins in patients with type 2 diabetes

Public title

The effects of ginger on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with type 2 diabetes, patients newly diagnosed diabetes to 10 years, no pregnancy and lactation, lack of vitamin and mineral supplementation, without any thyroid, kidney, CVD diseases and not using TG & cholesterol lowering drugs, and also using ESTROGEN or PROGESTRON, FBS<180, 2Hpp<250. Exclusion criteria: using insulin

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **84****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**

University of Medical Sciences and Health Services

Street addressUniversity of Medical Sciences and Health Services-
Bahonar sq-YAZD**City**

yazd

Postal code**Approval date**

2011-03-12, 1389/12/21

Ethics committee reference number

17/1/135711/پ

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

Diabetes

ICD-10 code

E11

ICD-10 code description

Diabetes

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

FBS

Timepoint

Before and 2 months after intervention

Method of measurement

mg/dl

2**Description**

fasting insulin

Timepoint

Before and 2 months after intervention

Method of measurement

mU/L

3**Description**

Fructose amin

Timepoint

Before and 2 months after intervention

Method of measurement

microm/L

4**Description**

HbA1C

Timepoint

Before and 2 months after intervention

Method of measurement

%

5**Description**

TG

Timepoint

Before and 2 months after intervention

Method of measurement

mg/dl

6**Description**

cholesterol

Timepoint

Before and 2 months after intervention

Method of measurement

mg/dl

7**Description**

LDL-C

Timepoint

Before and 2 months after intervention

Method of measurement

mg/dl

8**Description**

HDL-C

Timepoint

Before and 2 months after intervention

Method of measurement

mg/dl

9

Description

LDL-C/HDL-C

Timepoint

Before and 2 months after intervention

Method of measurement

-

10

Description

APO-A1

Timepoint

Before and 2 months after intervention

Method of measurement

ng/dl

11

Description

APO-B100

Timepoint

Before and 2 months after intervention

Method of measurement

ng/dl

12

Description

insulin resistance, sensitivity

Timepoint

Before and 2 months after intervention

Method of measurement

-

13

Description

-

Timepoint

-

Method of measurement

-

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

control: capsules 1 gr microcrystalin cellulose, 3times per day

Category

Treatment - Drugs

2

Description

intervention: capsules ginger 1 gr 3timea per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Behrouz Talaei Khales soflaei

Street address

jomhuri blv- YAZD

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medical Sciences and Health Services

Full name of responsible person

Dr Hassan Mozaffari

Street address

Bahonar sq.Yazd

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Medical Sciences and Health Services

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

Yazd Diabetes Research Center

Full name of responsible person

Dr Seyed Mohammad Mohammadi

Position

Endocrinologist

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

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences and Health Services

Full name of responsible person

Behrouz Talaei Khales Soflaei

Position

MS student of Health Science in Nutrition

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Medical Sciences and Health Services

Full name of responsible person

Dr Hassan Mozaffari

Position

PhD, nutritionist

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Email

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