

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The comparison of sour and green tea effect on glucose, lipid profile, oxidative stress and insulin resistance in patients with type 2 diabetes

Protocol summary

Summary

This investigation is a randomized controlled clinical trial with newly diagnosed diabetic patients (to 5 years) aged 30-60 years. They are assigned to two groups, green tea (50 patients) and sour tea (50 patient), based on random numbers table. Patients receive green and sour tea 3 times a day, 3 gram each time for 4 weeks. Blood pressure, FBS, Fructose amin, lipid (triglyceride, Total Cholesterol, HDL, LDL), fasting insulin, insulin resistance, insulin sensitivity, function of B cells and oxidative stress (MDA) are measured before and after the time of the intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107317161N1**

Registration date: **2011-10-16, 1390/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-16, 1390/07/24

Registrant information

Name

Zeinab Ahadi

Name of organization / entity

Yazd University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 35 1724 9333

Email address

z.ahadi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences and Health Services

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of sour and green tea effect on glucose, lipid profile, oxidative stress and insulin resistance in patients with type 2 diabetes

Public title

The comparison of sour and green tea effect on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 30 to 60 years; newly diagnosed diabetes to 5 years; $25 < \text{BMI} < 40 \text{ Kg/m}^2$; $80 < \text{FBS} < 250 \text{ mg/dl}$; not using Insulin; not using vitamin/mineral and antioxidant supplementation and fish oil until 6 months before intervention; without any thyroid, kidney, liver, CVD diseases. Exclusion criteria: having allergy to green or sour tea; preferring not to drink tea, having changes in diet or medicine therapy.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd University of Medical Sciences and Health Services

Street address

Bahonar sq.

City

Yazd

Postal code

Approval date

2011-03-12, 1389/12/21

Ethics committee reference number

17/1/135707/پ

Health conditions studied

1

Description of health condition studied

Diabetes II

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

TG

Timepoint

Before and 4 weeks after intervention

Method of measurement

Glycerol oxidase

2

Description

HDL-C

Timepoint

Before and 4 weeks after intervention

Method of measurement

Cholestrol oxidase

3

Description

FBS

Timepoint

Before and 4 weeks after intervention

Method of measurement

Glucose Oxidase

4

Description

TC

Timepoint

Before and 4 weeks after intervention

Method of measurement

Cholestrol Oxidase

5

Description

LDL-C

Timepoint

Before and 4 weeks after intervention

Method of measurement

Fridwald

6

Description

Fasting Insulin

Timepoint

Before and 4 weeks after intervention

Method of measurement

ELISA

7

Description

Insulin Resistance

Timepoint

Before and 4 weeks after intervention

Method of measurement

HOMA Calculator for excel ver 2.2(diabetes trials unit university of oxford)

8

Description

Insulin Sensitivity

Timepoint

Before and 4 weeks after intervention

Method of measurement

HOMA Calculator for excel ver 2.2(diabetes trials unit university of oxford)

9

Description

Function of B cells

Timepoint

Before and 4 weeks after intervention

Method of measurement

HOMA Calculator for excel ver 2.2(diabetes trials unit university of oxford)

10

Description

Fructose amin

Timepoint

Before and 4 weeks after intervention

Method of measurement

Tetra Nitro blue

11

Description

MDA

Timepoint

Before and 4 weeks after intervention

Method of measurement

Thiobarbituric Acid

Secondary outcomes

empty

Intervention groups

1

Description

Patients consume daily 450 mL (3 cups) sour tea for 4 weeks after breakfast and 2 hours after meal

Category

Treatment - Other

2

Description

Patients consume daily 450 mL (3 cups) green tea for 4 weeks after breakfast and 2 hours after meal

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences and Health Services

Full name of responsible person

Dr. Hassan Mozaffari

Street address

Bahonar sq.

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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. Afkhami

Position

Endocrinologist

Other areas of specialty/work

Street address

Jomhouri blvd, Afshar Hospital Alley

City

Yazd

Postal code

Phone

+98 35 1724 9333

Fax

Email

mozaffari.kh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences and Health Services

Full name of responsible person

Dr. Hassan mozaffari

Position

PhD, nutritionist

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

Bahonar sq.

City

Yazd

Postal code**Phone**

+98 35 1724 9333

Fax**Email**

mozaffari.kh@gmail.com

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

Daneshju Blvd, Yazd University of Medical Sciences
and Health Services

City**Postal code****Phone****Fax****Email****Web page address****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

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

Yazd University of Medical Sciences and Health
Services

Full name of responsible person

Zeinab Ahadi

Position