Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Cholestrol, 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
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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 < BMI <40 Kg/m2; 80 < FBS < 250 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
Glocose 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
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Endocrinologist
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Person responsible for scientific inquiries

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Name of organization / entity
Yazd University of Medical Sciences and Health Services

Full name of responsible person
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Person responsible for updating data

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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