

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of chamomile tea on depression status, glycemic control, Blood lipid profiles and oxidative stress in depressed patients with type 2 diabetes

Protocol summary

Summary

This investigation is a randomized controlled clinical trial to determine the effect of chamomile tea consumption on depression status, glycemic control, Blood lipid profiles and oxidative stress in depressed patients with type 2 diabetes. Inclusion criteria consists of: minimum 5 and maximum 15-year history of diabetes, mild to moderate depression (Beck test score of 35-11), age between 30 and 60 years old, patients with dyslipidemia, and exclusion criteria are: major depression (Beck test score greater than 30), which requires special treatment, people that during the interview noticed Thoughts of suicide, self-injury and a history of such in them, Pregnancy and lactation, history of hospitalization for mental illness liver disease, kidney, heart disease, thyroid disease, and central nervous system as the express themselves and etc. According to Beck depression test, people who have mild to moderate scores (Beck test score of 30-11) and do not use drugs, are selected. The sample size of study is 74 cases. patients were randomly divided into two groups: control group (receiving chamomile tea) and control (black tea recipient) 3 times a day for 12 weeks are divided. each groups will receive daily 3 cups of tea (each cups contain a 2.5 grams of tea bag in 150cc boiled water). In the beginning, after the 6 week and the end of the study using the Beck depression inventory, the severity of depression will be assessed. Serum lipids, HbA1c and Indicators of oxidative stress including total antioxidant capacity and malondialdehyde in both groups before and after the intervention will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112820132N1**

Registration date: **2015-03-15, 1393/12/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name

Sahar Kermanian smailabad

Name of organization / entity

Shahid Sadooghi University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

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+98 35 3624 0691

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kermaniansahar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences and Health Services

Expected recruitment start date

2015-02-19, 1393/11/30

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chamomile tea on depression status,

glycemic control, Blood lipid profiles and oxidative stress in depressed patients with type 2 diabetes

Public title

Effect of Chamomile tea consumption in the treatment of depressed patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Those aged between 60-30 years with mild to moderate depression (Beck test score of 30-11). no disorders and diseases of the kidney, liver, heart, thyroid, bleeding disorders and malignancies, autoimmune diseases, and degenerative diseases of the central nervous system as they express themselves, no history of hospitalization for mental illness, not using nutritional and antioxidant supplementation and sedative and diuretics during the last 3 months, diabetes mellitus type 2 (minimum 5 and maximum 15-year history of diabetes), and usage of blood glucose lowering drugs, patients with dyslipidemia who the usual treatment continues, Pregnant and lactating absence and lack of events such as job loss, divorce or death of their relatives during the last 3 months. Exclusion criteria: having allergy to chamomile, major depression (Beck test score greater than 30), which requires special treatment, , people that during the interview noticed Thoughts of suicide, self-injury and a history of such in them and preferring not to drink tea.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **74**

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**

Ethics Committee of Shahid Sadooghi University of

Medical Sciences and Health Services in Yazd, Iran

Street address

Educational Research Center, Imam Reza, Next to the Governor, Daneshjo BLV

City

Yazd

Postal code

8916189165

Approval date

2014-11-16, 1393/08/25

Ethics committee reference number

17/1/164966/پ

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

depression

ICD-10 code

F32, F33

ICD-10 code description

Depressive episode, Recurrent depressive disorder

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

depression

Timepoint

Baseline, after 6 weeks of intervention and At the end of the intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes**1****Description**

HbA1c

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Chromatography

2**Description**

LDL_C

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Freidwald's formula

3**Description**

HDL_C

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Colorimetry

4**Description**

TG

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Colorimetry

5**Description**

TC

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Colorimetry

6**Description**

TAC

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Reduction DPPH

7**Description**

MDA

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

Thiobarbituric Acid

Intervention groups**1****Description**

Intervention group will receive daily 3 cups of Chamomile tea at least half an hour after the meal for 12 weeks(each cup of Chamomile tea is produced by putting Chamomile tea bag contains 2.5 grams in 150 cc of boiled water). chamomile tea bags will be purchased from the Iranian Institute of Medicinal Plants. All the patients will receive the Tea bags on every 4 weeks base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.

Category

Treatment - Drugs

2**Description**

control group 3 cups of black tea daily the same period (each cup of black tea is produced by putting black tea bag contains 2.5 grams in 150 cc of boiled water at least half an hour after eating the meal)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Diabetes Research Center

Full name of responsible person

Doctor H. Mozaffari Khosravi

Street address

Bahonar Square, Yazd

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Sadooghi University of Medical Sciences and Health

Full name of responsible person

Prof. Hassan Mozaffari Khosravi

Street address

Imam Reza integrated, Blvd student, Yazd

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Sadooghi University of Medical Sciences and Health

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**

Shahid Sadooghi University of Medical Sciences and Health Services in Yazd

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Position

PhD Nutrition

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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