Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone

+98 35 3624 0691

Email address

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 the 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 continue, 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
Yazd

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
Full name of responsible person
Prof. Hassan Mozaffari Khosravi
Position
PhD Nutrition
Other areas of specialty/work

Street address
Imam Reza integrated, Blvd student, Yazd
City
Yazd
Postal code
Phone
+98 35 3624 0691
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
Prof. Hassan Mozaffari Khosravi
Position
PhD Nutrition
Other areas of specialty/work
Street address
Imam Reza integrated, Blvd student, Yazd
City
Yazd
Postal code
Phone
+98 35 3624 0691
Fax
Email
mozaffari.kh@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Sadooghi University of Medical Sciences and Health Services in Yazd
Full name of responsible person
Sahar kermanian smailabad
Position
Graduate student in Nutrition and Health Sciences
Other areas of specialty/work
Street address
Imam Reza integrated, Blvd student, Yazd
City
Yazd
Postal code
Phone
Fax
+98 36238555
Email
kermaniansahar@gmail.com
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