Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Effect of Chamomile tea consumption on metabolic status, oxidative stress and inflammation in Type 2 diabetic patients

Protocol summary

Summary

In this study, patients who referred to an endocrinologist, will be assessed in order to determine the Effects of Chamomile tea consumption on metabolic status, oxidative stress and inflammation in type 2 diabetic patients. Inclusion criteria consists of: at least 6 months history of diabetes; usage of blood sugar lowering drugs; age between 30 and 60 years old and exclusion criteria are: Pregnancy and lactation; liver disease, kidney, heart disease, thyroid disease, and inflammatory disease. Thirty two subjects will be divided into two groups randomly (taking Chamomile tea and control). Intervention groups will receive daily 3 cups of chamomile tea (each cups contain a 3 grams of Chamomile tea bag in 150cc boiled water) immediately after the meal for 8 weeks and we will recommend the control group to use the same amount of boiled water daily instead of Chamomile tea in this period. Every 2 weeks, Compounds will be delivered to people. For each Patient questionnaire will be filled and general characteristics، anthropometric measurements (height and weight to calculate BMI) will be assessed. For each patient, 24-h recall questionnaire will be filled in order to assessment of food intake for 3 days a week (2 working days and 1 holiday). These questionnaires will be completed at baseline، end of 4th week and 8th week of the study. Ten ml blood sample from each patient will be taken after 12-14 hours fasting at the beginning and end of the intervention, and fasting blood glucose levels, HbA1c, fasting serum insulin, insulin resistance, serum lipids, hs-CRP, TNF-a and Indicators of oxidative stress including total antioxidant capacity, malondialdehyde , catalase, glutathione peroxidase and superoxide dismutase in both groups before and after the intervention will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012712299N1**
Registration date: **2013-04-05, 1392/01/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-04-05, 1392/01/16

Registrant information

Name
Maryam Zemestani
Name of organization / entity
Tabriz University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Nutritional Research Center of Tabriz University of Medical Sciences, Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Chamomile tea consumption on metabolic status, oxidative stress and inflammation in Type 2 diabetic patients

Public title
Effect of Chamomile tea consumption in the treatment of patients with Type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Type 2 diabetes for at least 6 months, age between 30-60 years, usage of blood glucose lowering drugs Exclusion criteria: usage of nutritional supplements in the past 3 months or during the study, usage of insulin, Pregnancy or lactation, BMI more than 37, Renal failure, liver disease, Cardiovascular disease, thyroid disorders, History of allergy, smoking, alcohol usage, Following a specific diet, Taking corticosteroids or immunosuppressive drugs
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Random allocation method is Block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Golbad Street, Tabriz University of Medical Sciences
City
Tabriz
Postal code
Approval date
2013-02-20, 1391/12/02
Ethics committee reference number
91208

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E10,E11,E1
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting blood glucose
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
Enzymatic colorimetric

2

Description
Fasting insulin serum
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
ELISA assay

3

Description
HbA1C (Glycosilated hemoglobin)
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
ELISA

4

Description
Insulin resistance
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
HOMA-IR calculation

5

Description
Lipid profiles (TC, TG, LDL-C, HDL-C)
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
Enzymatic methods for TC,TG and HDL-C For LDL-C : Freidwald’s formula: LDL-C = TC- HDL-C - (TG/5)

6

Description
serum malondialdehyde(MDA)
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
spectrophotometry

7

Description
serum total antioxidant capacity
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
spectrophotometry

8

Description
GPX activity
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
spectrophotometry

9

Description
SOD activity
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
spectrophotometry

10

Description
catalase enzyme activity
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
spectrophotometry

11

Description
hc-CRP
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
immunoturbidimetry

12

Description
TNF-a
Timepoint
Baseline and after 8 weeks of intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Macronutrients intake
Timepoint
before and after 8 weeks intervention
Method of measurement
24-h recall Questionnaire

2

Description
Anthropometric index(weight and Body Mass Index)
Timepoint
before and after 8 weeks intervention
Method of measurement
Analogue scale for weight and weight(Kg)/Square Height for body mass index

Intervention groups

1

Description
Intervention group will receive daily 3 cups of Chamomile tea immediately after the meal for 8 weeks(each cup of Chamomile tea is produced by putting Chamomile tea bag contains 3 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 two 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 lukewarm boiled water daily over the same period (per cup after meal consumption)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology clinic of Tehran Imam Hussein Hospital
Full name of responsible person
Maryam Zemestani
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nutritional Research Center of Tabriz University of Medical Sciences

Full name of responsible person
Alireza Ostadrahimi

Street address
Nutrition School, Attare Neishaboori Avenue, Golgasht Street

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Nutritional Research Center of Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person
Seyed Kazem Shakouri

Street address
Golbad Street

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for Research, Tabriz University of Medical Sciences

Proportion provided by this source

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
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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