

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of chamomile infusion consumption on metabolic responses and renal function biomarkers in patients with type 2 diabetes with diabetic participants who do not receive this intervention .

Protocol summary

Summary

This study was designed to evaluate the effects of chamomile flower infusion on serum lipids, blood glucose and kidney functions in patients with type 2 diabetes. In this clinical trial, 40 volunteers with type 2 diabetes (male and female) aged 30–70 years will randomly allocate in two groups: intervention or control group. The intervention group will consume chamomile herbal tea (10g/100 ml hot water) two times per day before meals (lunch and dinner) for 4 weeks. No intervention will be done in control group. Exclusion criteria will include insulin treatment, history of diseases including liver, kidney and cancer, following a specific diet, regular exercise and having allergy to chamomile plant. Fasting blood glucose, 2 hour postprandial blood glucose, total cholesterol, triglyceride, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, creatinine and urea will evaluate at the baseline and at the end of the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120918329N2**

Registration date: **2015-07-26, 1394/05/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-26, 1394/05/04

Registrant information

Name

Fatemeh Kaseb

Name of organization / entity

Diabetes Research Center, Shahid Sadoughi
University of medical sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3821 5197

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Diabetes Research Center,
Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of chamomile infusion consumption on metabolic responses and renal function biomarkers in patients with type 2 diabetes with diabetic participants who do not receive this intervention .

Public title

Effect of chamomile infusion on blood glucose, lipid profile and serum kidney functions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with type 2 diabetic aged over the 30 years; not having a history of gastrointestinal,

renal, hepatic and heart disorders or allergic reactions to chamomile plant; not being under insulin therapy. Exclusion criteria: consuming less than 30 % of the packed chamomile; changing the dose of medicines within the last 6 months or during the intervention; following a specific diet and changing their physical activity.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 Sadoughi University of medical sciences

Street address

Talare Honar Alley, Shahid Sadoughi Blvd.

City

Yazd

Postal code**Approval date**

2014-08-17, 1393/05/26

Ethics committee reference number

17/1/102014/پ

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

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

Fasting blood glucose

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

2**Description**

2hour postprandial blood glucose

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

3**Description**

Total cholesterol

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

4**Description**

Triglyceride

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

5**Description**

Low density lipoprotein

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

6**Description**

High density lipoprotein

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

Secondary outcomes

1

Description

Creatinine

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

2

Description

Urea

Timepoint

At the start of intervention and 4 weeks after the intervention

Method of measurement

Blood biochemical tests

Intervention groups

1

Description

Intervention group: This group will consume one cup of chamomile herbal tea (10 grams of chamomile flowers infuse for 10 min in 100 mL hot water without sugar) two times a day before meals (lunch and dinner) for 4 weeks. The chamomile flowers will procure from the local market of Yazd.

Category

Other

2

Description

Control group: No intervention will be done in this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zeinab Zare

Street address

Talare Honar Alley, Shahid Sadoughi Blvd.

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahid Sadoughi University of medical sciences, Yazd, Iran

Full name of responsible person

Nasim Namirani (The contact person of the vice chancellor for research)

Street address

Talare Honar Alley, Shahid Sadoughi Blvd.

City

Yazd

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 of Shahid Sadoughi University of medical sciences, Yazd, Iran

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 Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zeinab Yazdanpanah

Position

MSc student of Health Sciences in Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Fatemeh Kaseb

Position

PhD in Nutrition

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Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zeinab Yazdanpanah

Position

MSc student of Health Sciences in 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