

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

##### Email address

fkaseb@ssu.ac.ir

##### 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

##### Street address

Department of Health, Imam Reza Institute, Student Blvd, Imam Hossein Sq.

##### City

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##### Postal code

##### Phone

+98 35 3526 3237

##### Fax

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yazd456@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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**Full name of responsible person**

Fatemeh Kaseb

**Position**

PhD in Nutrition

**Other areas of specialty/work****Street address**

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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

**Other areas of specialty/work****Street address**

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Blvd, Imam Hossein Sq.

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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*