

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of sour tea consumption (*Hibiscus sabdariffa* L.) on the lipid profile in dyslipidemic subjects

#### Protocol summary

##### Summary

In this randomized clinical trial, inclusion criteria are: having polygenic dyslipidemia as defined, not taking lipid lowering drugs and exclusion criteria are: having allergy to tea, not interested in consuming tea; having other diseases such as familial dyslipidemia, diabetes, cardiovascular disease, kidney and liver diseases. 50 patients after signing informed consent will be entered to the study. The patients will be randomly assigned into two intervention and control groups. Both groups at baseline will receive lifestyle modification education. The intervention period will be 12 weeks, in which the intervention group will consume two cups of sour tea extract daily between morning and evening meals for 90 days (each time, add two teaspoons (2 grams) of pulverized sour tea in one glass of boiling water (240 ml) for 30 minutes, with a sugar cube (3 g)). The Intervention group will be assessed and followed of possible complications of consuming sour tea. In both groups total cholesterol, triglyceride, LDL-c, HDL-c will be measured at baseline, and six weeks and twelve weeks after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008224612N1**

Registration date: **2012-04-30, 1391/02/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-04-30, 1391/02/11

##### Registrant information

Name

Farihe Ahmadzadeh Sani

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 53 3722 1929

##### Email address

farihe\_ahmadzadeh1384@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

The International Branch of Shahid Beheshti University of Medical Sciences & Health Services

##### Expected recruitment start date

2011-12-22, 1390/10/01

##### Expected recruitment end date

2012-09-20, 1391/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of sour tea consumption (*Hibiscus sabdariffa* L.) on the lipid profile in dyslipidemic subjects

##### Public title

The effect of sour tea (*Hibiscus sabdariffa* L.) on the lipid

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Polygenic dyslipidemia as defined; not intaking lipid lowering drugs Exclusion criteria: allergy to tea; not interested in consuming tea; take a trip; having other diseases such as familial dyslipidemia; diabetes; cardiovascular disease; kidney and liver diseases

##### 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: **80**

**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**

Medical Ethics Committee of the International Branch of Shahid Beheshti University of Medical Scien

**Street address**

19 Shahid Abbaspour St., Vali-Asr Ave., the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**City**

Tehran

**Postal code**

141553693

**Approval date**

2012-01-01, 1390/10/11

**Ethics committee reference number**

116/5237

**Health conditions studied**

1

**Description of health condition studied**

polygenic Dyslipidemia

**ICD-10 code**

E78.2

**ICD-10 code description**

Mixed hyperlipidaemia

**Primary outcomes**

1

**Description**

total cholesterol

**Timepoint**

Baseline, six weeks and twelve weeks after intervention

**Method of measurement**

Cholesterol oxidase enzymatic method

**Secondary outcomes**

1

**Description**

LDL-C

**Timepoint**

Baseline, six weeks and twelve weeks after intervention

**Method of measurement**

Fridvald is calculated using the formula

2

**Description**

HDL-c

**Timepoint**

Baseline, six weeks and twelve weeks after intervention

**Method of measurement**

Cholesterol oxidase enzymatic method

3

**Description**

triglyceride

**Timepoint**

Baseline, six weeks and twelve weeks after intervention

**Method of measurement**

Glycerol oxidase enzymatic methods

**Intervention groups**

1

**Description**

Intervention group: The Intervention group will receive lifestyle modification education at baseline and then consume two cups of sour tea extract daily between morning and evening meals for 90 days (each time, add two teaspoons (2 grams) of pulverized sour tea in one glass of boiling water (240 ml) for 30 minutes, and take it with a sugar cube (3 grams)).

**Category**

Treatment - Other

2

**Description**

Control group: The Control group will receive lifestyle modification education at baseline only and do not consume sour tea.

**Category**

Lifestyle

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Gonabad,s 22 Bahman Hospital

**Full name of responsible person**

Farihe Ahmadzadeh Sani

**Street address**

Gonabad University of Medical Sciences, Food and Drug Administration, Ghadir Square

**City**

Gonabad

**Street address**

Gonabad University of Medical Sciences, Food and Drug Administration, Ghadir Square

**City**

Gonabad

**Postal code**

9691699967

**Phone**

+98 53 3722 1929

**Fax**

+98 53 3722 1919

**Email**

farihe\_ahmadzadeh1384@gmu.ac.ir

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**Full name of responsible person**

Dr.Kiandokht Ghanati

**Street address**

19 Shahid Abbaspour St., Vali-Asr Ave., the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**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**

the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**Full name of responsible person**

Farihe Ahmadzadeh Sani

**Position**

MSc.student in nutrition sciences

**Other areas of specialty/work**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**Full name of responsible person**

Farihe Ahmadzadeh Sani

**Position**

MSc.student in nutrition sciences

**Other areas of specialty/work**

**Street address**

Gonabad University of Medical Sciences, Food and Drug Administration, Ghadir Square

**City**

Gonabad

**Postal code**

9691699967

**Phone**

+98 53 3722 1929

**Fax**

+98 53 3722 1919

**Email**

farihe\_ahmadzadeh1384@gmu.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

the International Branch of Shahid Beheshti University of Medical Sciences & Health Services

**Full name of responsible person**

Farihe Ahmadzadeh Sani

**Position**

MSc.student in nutrition sciences

**Other areas of specialty/work**

**Street address**

Gonabad University of Medical Sciences, Food and Drug Administration, Ghadir Square

**City**

Gonabad

**Postal code**

9691699967

**Phone**

+98 53 3722 1929

**Fax**

+98 53 3722 1919

**Email**

farihe\_ahmadzadeh1384@gmu.ac.ir

**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*