

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessing the effect of ginseng in reducing the severity of fatigue in individuals with idiopathic chronic fatigue

Protocol summary

Study aim

Assessing the effect of ginseng in reducing the severity of fatigue in individuals with idiopathic chronic fatigue

Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

Settings and conduct

This double blinded study will be performed in private clinic. At base line and after 4 weeks of intervention with supplement/placebo, fatigue severity will be assessed using fatigue severity scale (FSS) questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years, Willing to participate in the study, Having chronic idiopathic fatigue based on internist diagnosis Exclusion criteria: Pregnancy and lactation, Having diabetes, Having known cardiovascular disease, Having known renal disease, Having any types of cancer

Intervention groups

Patients will receive 500 mg Ruginseng (Ghaem Daro) capsule or placebo two times daily for 8 weeks. Each capsule contains ginseng or maltodextrine in placebo group.

Main outcome variables

fatigue severity using fatigue severity scale (FSS) questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N20**

Registration date: **2022-05-17, 1401/02/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-17, 1401/02/27**

Update count: **0**

Registration date

2022-05-17, 1401/02/27

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of ginseng in reducing the severity of fatigue in individuals with idiopathic chronic fatigue

Public title

Effect of ginseng in reducing the severity of fatigue in individuals with idiopathic chronic fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-65 years Willing to participate in the study
Having chronic idiopathic fatigue based on internist diagnosis

Exclusion criteria:

Pregnancy and lactation Having diabetes Having known cardiovascular disease Having known renal disease Having any types of cancer

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people: participants, research team including principle investigator, data collectors, and outcome assessors will be blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti medical university

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2022-02-27, 1400/12/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1072

Health conditions studied

1

Description of health condition studied

Chronic fatigue

ICD-10 code

R53.82

ICD-10 code description

Chronic fatigue, unspecified

Primary outcomes

1

Description

fatigue severity

Timepoint

Before and after 4 weeks of intervention

Method of measurement

fatigue severity scale (FSS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg Ruginseng (Ghaem Daro) capsule two times daily for 4 weeks

Category

Treatment - Other

2

Description

Control group: Placebo contain maltodextrine, 500 mg, (Ghaem darou company), two times daily for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Soodeh Razeghi Jahromi

Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

193954741

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

193954741

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

City

Tehran

Province

Tehran

Postal code

193954741

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data would be available to public

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

Sending email

Comments