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
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Iran (Islamic Republic of)
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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
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No. 46, West Arghavan St., Farahzadi Blv., Qods Town
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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
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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
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Person responsible for updating data

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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