

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of astragalus root extract on chronic fatigue syndrome in nurses

Protocol summary

Study aim

Determining the effect of root extract on chronic fatigue syndrome in nurses working in medical centers in Kashan, Aran and Bidgol cities in 1401.

Design

Clinical trials with a control group, with parallel groups, triple-blind, and randomized. Online Sealedenvelope software was used for randomization.

Settings and conduct

Nurses working in the medical centers of Kashan, Aran, and Bidgol, who are diagnosed with chronic fatigue based on a questionnaire, are randomly assigned to two control and experimental groups. The intervention group will receive 500 mg capsules containing the root extract and the control group will receive a placebo (starch) twice a day for one month. The questionnaire is reviewed at the beginning, end and one month after the end. Participants, drug prescriber (the drugs will be placed in similar packages and will be marked with a code), and statistical analyst (group names will be recorded in SPSS in short) Information does not about the group to which the participants have been assigned.

Participants/Inclusion and exclusion criteria

Inclusion criteria: It must meet the criteria for chronic fatigue syndrome. The age should be 20 to 50 years. A nurse working in a hospital. Exclusion Criteria: Take anticoagulants. take antipsychotic drugs. Have thyroid disorders in the form of hyperactivity or hypoactivity.

Intervention groups

Intervention group: The root extract (hydroalcoholic), in the form of 500 mg capsules, is taken twice a day (morning and night), one capsule each time. Control group: they received capsules containing corn starch (500 mg per capsule) twice a day for one month, which does not differ from the root extract in terms of appearance.

Main outcome variables

Chronic fatigue syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100124003146N11**

Registration date: **2023-03-01, 1401/12/10**

Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**

Update count: **0**

Registration date

2023-03-01, 1401/12/10

Registrant information

Name

Ismail Azizi-Fini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

azizi-es@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-16, 1401/12/25

Expected recruitment end date

2023-06-15, 1402/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of astragalus root extract on chronic fatigue syndrome in nurses

Public title
The effect of astragalus root extract on chronic fatigue syndrome in nurses

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Have criteria for chronic fatigue syndrome. 20 to 50 years old. A nurse working in a hospital. Willingness to participate in the study
Exclusion criteria:
Unwillingness to continue participating in the study Not taking medicine for 4 consecutive days Lack of access to samples receiving anticoagulants (warfarin-aspirin-coumadin) Blood pressure drop (systole less than 100 and diastole less than 60) during study continuously or intermittently during the day

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used in this study. First, the randomization list will be prepared using the online randomization software in blocks of 4. The letter A will be chosen for the intervention group and the letter B will be chosen for the placebo group. Sampling is continuous and then the samples with entry conditions will be placed in groups in order and one after the other based on the previously prepared list of the output of www.sealedenvelop.com online randomization software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The present study is triple blind. The participants will not know the type of group they will be assigned to and will only receive the capsule containing the drug or starch. It should be noted that the drug and placebo are poured into gelatin capsules of the same color. In addition, both substances are white, so the participants cannot notice the type of group when they open the capsules. The second blinding is related to the person prescribing the medicine, who will receive the prepared medicines inside the coded plastic envelopes, and after referring the participant to him, the prescription referee and the code of the envelope will be recorded in the participant's sheet. The third blinded person will be a statistical analyst, whose names of the groups will be entered in

the SPSS software and will be available to him.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Nursing and Midwifery, Health and Paramedicine - Kashan University of Medical Sciences
Street address
Qutb Rawandi Blvd
City
kashan
Province
Isfahan
Postal code
8715981151

Approval date
2023-02-13, 1401/11/24

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1401.088

Health conditions studied

1

Description of health condition studied
Chronic fatigue syndrome

ICD-10 code
G93.3

ICD-10 code description
Postviral fatigue syndrome

Primary outcomes

1

Description
Chronic fatigue syndrome

Timepoint
At the beginning of the study (before the start of the intervention), the end of the intervention, one month after the end of the intervention.

Method of measurement
DePaul Symptom Questionnaire - Short Form (DSQ-SF)

Secondary outcomes

1

Description

anxiety
Timepoint
At the beginning of the study (before the start of the intervention), the end of the intervention, one month after the end of the intervention.
Method of measurement
Beck Anxiety Inventory

2

Description
sleep quality
Timepoint
At the beginning of the study (before the start of the intervention), the end of the intervention, one month after the end of the intervention.
Method of measurement
Pittsburgh Sleep Quality Index

Intervention groups

1

Description
Intervention group: Intervention group: In this study, the root extract extracted in hydroalcoholic form is prepared by Barij-Essance company in 500 mg capsules and will be given to the intervention group samples for one month to consume one capsule twice a day (morning and night).
Category
Treatment - Drugs

2

Description
Control group: The samples randomly assigned to the control group received capsules containing corn starch (500 mg per capsule provided by Barij-essence) twice a day for one month, which did not differ in appearance from the root extract.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
zahra sadat banihashemi
Street address
Kashan Qutb Ravandi Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
Street address
Kashan Qutb Ravandi Blvd. University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr Ismail Azizi-Fini
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

the results related to the main outcome will be distributed.

When the data will become available and for how long

Access will start from the time the results are printed to forever.

To whom data/document is available

Academic and industrial researchers are allowed to submit data requests.

Under which criteria data/document could be used

The applicant must clearly state the purpose of the data request to the person in charge of the data, and if approved by the University Research Council, non-identifiable data will be provided to him.

From where data/document is obtainable

Dr. Ismail Azizi Fini, email: azizifinies@yahoo.com

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

The data will be sent in less than 24 hours after sending the request via email.

Comments