Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 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
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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
Isfehan
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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Isfehan

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Email

abc.zariii@gmail.com

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

Nursery

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Person responsible for scientific inquiries

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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
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