Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

The effect of the edible product prepared from mountain pistachio (Pistacia atlantica) on fatigue

Protocol summary

Study aim
The effect of the edible product prepared from mountain pistachio (Pistacia atlantica) on fatigue

Design
The clinical trial with two intervention and control groups, in a parallel, randomized and three-blind manner, will be conducted on 80 volunteers with simple randomization.

Settings and conduct
This study will be clinical, randomized and three-way blind and will be conducted on qualified armed forces soldiers at Ayatollah Khatami barracks in Yazd with a sample size of approximately 80 people. 15 cc of traditional medicine product as well as placebo will be given daily to two intervention and control groups. The level of fatigue before and after the intervention will be measured with Smets Multidimensional Fatigue Measurement Questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All soldiers are serving in the same unit (in terms of job description). People should be in the age range of 18 to 26 years. Obtaining consent to enter the study and continue it. Ability to track people. Not taking medicine for the existing complaint two weeks before the start of the study. Exclusion criteria: Presence of acute or chronic illness (including diabetes, hypertension, hyperlipidemia, severe weight loss, and hypothyroidism) in soldiers based on data collected in the interview. History of any type of allergic reaction to pistachios, mountain pistachios, rose water or grape vinegar.

Intervention groups
Intervention group: Edible product containing mountain pistachios: 15 cc of the syrup will be given to the study subjects daily for 15 days. Control group: 15 cc of placebo syrup will be given to the study subjects daily for 15 days.

Main outcome variables
Fatigue indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170423033605N3**
Registration date: **2023-01-28, 1401/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**
Update count: **0**

Registration date
2023-01-28, 1401/11/08

Registrant information
Name
Abolfazl Dehghanpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3522 1596
Email address
a.dehghanpoor@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of the edible product prepared from mountain pistachio (Pistacia atlantica) on fatigue

Public title

The effect of mountain pistachio (Pistacia atlantica) on sold fatigue

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All soldiers must be serving in the same unit (in terms of job descriptions) Study subjects should be in the age range of 18 to 26 years Obtaining consent to enter the study and continue it Ability to track cases Not taking drug for the existing complaint two weeks before the start of the study

Exclusion criteria:

Presence of acute or chronic illness (including diabetes, hypertension, hyperlipidemia, severe weight loss, and hypothyroidism) in soldiers based on data collected in the interview History of any type of allergic reaction to pistachios, mountain pistachios, rose water or grape vinegar

Age

From **18 years** old to **26 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, we will use four block randomization method. For this purpose, we prepare four sheets of paper. On two sheets of paper we write the letters I meaning "Intervention" and on two sheets the letter P meaning "Placebo". We mix the sheets together and put them in the desk drawer. Upon the visit of each eligible patient, one of the sheets will be drawn randomly and based on whether the drawn sheet is I or P, they will be assigned to one of the two intervention or control groups. It should be noted that the drawn cards will not be returned to the table drawer until all four cards have been drawn. After randomly pulling out all four sheets, all the sheets will be returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size (80 patients) is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo will be prepared in similar containers by the respected pharmacist, and the smell of rose water and the combination of the taste of sugar and grape vinegar in both groups will prevent the blinding process from being disturbed. In this study, participants, researchers, clinical caregivers, outcome assessors and data analysts, as well as the safety and data monitoring committee, do not know which container is the drug and which is the placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The specialized committee of ethics in biomedical research of the University of Medical Sciences of

Street address

Quds settlement (west) - between South Flamak and Zarafshan, Simai Iran St. - Ministry of Health, Treatment and Medical Education headquarters, block A, 13th floor

City

Tehran

Province

Tehran

Postal code

1467664978

Approval date

2022-11-20, 1401/08/29

Ethics committee reference number

IR.AJAUMS.REC.1401.140

Health conditions studied

1

Description of health condition studied

Chronic Fatigue Syndrome

ICD-10 code

R53.82

ICD-10 code description

Chronic fatigue, unspecified

Primary outcomes

1

Description

Fatigue indicators

Timepoint

Fatigue measurement at the beginning of the study (before the start of the intervention) and 15 days after the start of the intervention

Method of measurement
Smets Multidimensional Fatigue Measurement Questionnaire

Secondary outcomes

1

Description
Marital status
Timepoint
Before intervention
Method of measurement
questionnaire

2

Description
Complications of intervention
Timepoint
Two weeks after the intervention
Method of measurement
questionnaire

3

Description
temperament
Timepoint
Before the intervention and two weeks after the intervention
Method of measurement
Mojahedi temperament questionnaire

4

Description
Body mass index
Timepoint
Before intervention
Method of measurement
Mass (kilograms) divided by height squared (centimeters)

Intervention groups

1

Description
Intervention group: Edible product containing mountain pistachios: 15 cc of the syrup will be given to the study subjects daily for 15 days. The edible product in the form of syrup contains pistachios, rose water, grape vinegar and sugar.
Category
Treatment - Drugs

2

Description
Control group: Placebo: 15 cc of syrup will be given to the study subjects daily for 15 days. Placebo is a syrup containing sugar, rose water and grape vinegar.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khatami Preparatory Martial School, Yazd
Full name of responsible person
Colonel Mahmoud Akhundi
Street address
Khizr Abad road, about 15 km from the city
City
Yazd
Province
Yazd
Postal code
8945133419
Phone
+98 35 3725 4396
Fax
Email
info@syazd.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
General Dr. Ramin Hamidi Farahani
Street address
West Fatemi St. - Shahid Etemadzadeh St
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
jps@ajaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences

Full name of responsible person
Abolfazl Dehghanpour

Position
physician & Traditional medicine specialist

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Imamshahr, Kargar Blvd., Farhang St., Alley 21, No. 12

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Yazd

Province
Yazd

Postal code
8917786888

Phone
+98 35 3522 1596

Email
adf442@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences

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physician & Traditional medicine specialist

Latest degree
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Person responsible for updating data

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Full name of responsible person
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Email
adf442@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Except for the participant data file, other parts of the study potentially can be shared after de-identification.

When the data will become available and for how long
The access period will start 6 months after the results are published.

To whom data/document is available
Study information will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data can be used in order to improve the level of soldiers' health, especially in terms of mental health, subject to obtaining permission from the main researcher and the Army University of Medical Sciences.

From where data/document is obtainable
Dr. Abolfazl Dehghanpour, Artesh University of Medical Sciences, Tehran - Fatemi West Street - Shahid

Etemadzadeh Street. Postal code: 1411718541 Phone: +98 21 8609 6350 Email: jps@ajaums.ac.ir

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

6 months after the publication of the article resulting from the results in one of the ISI journals, the applicant can apply by sending his/her request via email (to A.dehghanpoor@ssu.ac.ir) and obtaining permission to receive the data.

Comments