Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of zedoary medicinal plant (Curcuma zedoaria) on the fatigue of soldiers in military training course in Shiraz: a randomized double blind placebo-controlled clinical trial

Protocol summary

Study aim

Determination of fatigue in the intervention group before the study Determination of fatigue in the intervention group after the study Determination of fatigue in the placebo group before the study Determination of fatigue in the placebo group after the study Comparison of fatigue between the intervention and placebo groups before the study Comparison of fatigue between the intervention and placebo groups after the study

Design

A hundred of soldiers will randomly be selected from a garrison and divided into two 50 person groups of intervention and placebo. As for the randomization, The method of permutation blocks with 25 quadruple blocks will be used .

Settings and conduct

In the intervention group, each person will receive 2 capsules of zedoary powder (500 mg) per day for 15 days. In contrary, subjects in the placebo group will receive placebo capsules contain 500 mg of starch powder with a completely similar appearance twice a day for 15 days. The capsules of drug and placebo have the same size, color, and smell; thus, the trial will be double blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Training soldiers living in military garrison in Shiraz; Lack of chronic diseases; Signing the informed consent Exclusion criteria: Sensitivity to zedoary

Intervention groups

In the intervention group, each person will receive two 500 mg capsules of zedoary powder per day for 15 days. In the control group, each person will receive two 500 mg capsules of starch powder per day for 15 days.

Main outcome variables

Score of Multidimensional Fatigue Inventory questionnare

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130216012486N3**
Registration date: **2018-01-01, 1396/10/11**
Registration timing: **prospective**

Last update: **2018-01-01, 1396/10/11**
Update count: **0**

Registration date

2018-01-01, 1396/10/11

Registrant information

Name

Babak Daneshfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 8867

Email address

daneshfard@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of zedoary medicinal plant (Curcuma zedoaria) on the fatigue of soldiers in military training course in Shiraz: a randomized double blind placebo-controlled clinical trial

Public title
Effect of zedoary on fatigue
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Training soldiers living in military barracks in Shiraz Lack of chronic diseases Signing the informed consent
Exclusion criteria:
Sensitivity to zedoary
Age
No age limit
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization using statistical software will be done. The capsules of the drug and the placebo have the same size, color, and smell; thus neither soldiers nor the researcher will know the allocation and the trial will be conducted double blind.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the soldiers and the researcher will be blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of AJA University of Medical Sciences
Street address
Shahid Fatemi St., Col. Etemadzadeh St., AJA University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14185/611
Approval date
2017-11-29, 1396/09/08
Ethics committee reference number
IR.AJAUMS.REC.1396.84

Health conditions studied

1

Description of health condition studied
Relationship of the zedoary medicinal plant with the fatigue of soldiers in military training course
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score of Multidimensional Fatigue Inventory questionnare
Timepoint
At the beginning of the study and 15 after the start of taking the capsule
Method of measurement
Multidimensional Fatigue Inventory questionnare

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Shiraz Military Education Garrison
Full name of responsible person
Babak Daneshfard
Street address
Zand St., Setad Sq., Shiraz Medical School
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Babak Daneshfard
Street address
Zand St., Setad Sq., Shiraz Medical School, Shiraz, Iran
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Web page address
https://scholar.google.com/citations?user=quH0EbMAAAAJ&hl=en
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
Shiraz University of Medical Sciences
Full name of responsible person
Babak Daneshfard
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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
Informed consent
When the data will become available and for how long
6 months after publication
To whom data/document is available
Researchers
Under which criteria data/document could be used
Presenting the proposal
From where data/document is obtainable
Babak Daneshfard 09166725988
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What processes are involved for a request to access data/document
Direct contact
Comments