

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 questionnaire

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 questionnaire

Timepoint

At the beginning of the study and 15 after the start of taking the capsule

Method of measurement

Multidimensional Fatigue Inventory questionnaire

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

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Fax

+98 71 3234 5145

Email

babakdaneshfard@gmail.com

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

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Fax

+98 71 3234 5145

Email

babakdaneshfard@gmail.com

Web page address

<https://scholar.google.com/citations?user=quH0EbMAAAJ&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

Street address

Zand St., Setad Sq.

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Fax

+98 71 3234 5145

Email

babakdaneshfard@gmail.com

Person responsible for scientific 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

Street address

Zand St.

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Email

babakdaneshfard@gmail.com

Person responsible for updating data

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

Street address

Zand

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 5145

Email

babakdaneshfard@gmail.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

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

babakdaneshfard@gmail.com

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

Direct contact

Comments