

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of herbal medicine (Tiryage wabai) on anxiety, depression and sleep in the elderly: A double-blind randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of herbal combination medicine (Tiryage wabai) on anxiety, depression and sleep in the elderly

Design

Randomized double-blind clinical trials with control group, phase 3, on 108 patients that will be randomly assigned to the case or control group and will take one capsule of the drug or placebo daily, one hour before dinner, for 30 days.

Settings and conduct

Men and women 60 to 75 years refer to the health center randomly divided into two groups to record patient demographic information, blood pressure and medicines and herbal teas. The Hamilton Anxiety, BDI, and the PSQ Questionnaires will be complete. Measurements will be performed again after the intervention.

Participants/Inclusion and exclusion criteria

Men and women aged 60 to 75 years who referred to the health center of Karaj city who obtained more than a quarter of the score obtained from each of the three questionnaires of depression, sleep and anxiety and a history of sensitivity to each of the components used in They do not have the medicine and enter the study.

Intervention groups

They will be in the case or control group and will take one capsule of medicine or placebo daily one hour before dinner for 30 days.

Main outcome variables

depression and anxiety severity , sleep state

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211017052785N2**

Registration date: **2022-06-14, 1401/03/24**

Registration timing: **prospective**

Last update: **2022-06-14, 1401/03/24**

Update count: **0**

Registration date

2022-06-14, 1401/03/24

Registrant information

Name

Mina Maarefvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3464 3705

Email address

m.maarefvand@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of herbal medicine (Tiryage wabai) on anxiety, depression and sleep in the elderly: A double-blind randomized controlled clinical trial

Public title

The effect of herbal medicine (Tiryage wabai) on anxiety, depression and sleep in the elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women aged 60 to 75 years referred to the health center of Karaj city Having the desire and satisfaction to participate in the project Obtain more than a quarter of the score from each of the three Depression, Sleep, and Anxiety Questionnaires

Exclusion criteria:

Inability to take the drug in capsule form Do not have a history of allergies to any of the ingredients used in the medicine Do not change the amount of medication taken for any of the three conditions of anxiety, depression and sleep Have serious underlying conditions such as uncontrolled blood pressure or diabetes, untreated ischemic heart disease, kidney and liver failure.

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of individuals to the intervention and control groups will be done using block randomization method with the size of 4, 6 and 8 non-identical blocks (to hide the allocation). Statistical or web-based software such as <https://www.sealedenvelope.com/simple-randomiser/v1/lists> will be used for this purpose. In this method, the order of block size as well as the allocation of people in groups is randomly selected. In such a way that first 4, 6 or 8 blocks are randomly selected and in the selected block, the order of assigning individuals to the intervention and control group is determined randomly. In the study, they will be assigned to the intervention and control groups based on the production chain, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, medicine and placebo are prepared, packaged and numbered by the pharmacist and the project manager and sampler will not be informed of their contents. Patients are also unaware that the capsule is taking medication or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Alborz University of Medical Sciences

Street address

45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology

City

Alborz

Province

Alborz

Postal code

3198764653

Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.ABZUMS.REC.1401.050

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F34

ICD-10 code description

Persistent mood [affective] disorders

2**Description of health condition studied**

anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

anxiety Severity

Timepoint

Beginning and end of the study

Method of measurement

Hamilton Anxiety Questionnaire

2**Description**

depression severity

Timepoint

Beginning and end of the study

Method of measurement

Beck Depression Inventory BDI-II

3

Description

Sleep status

Timepoint

Beginning and end of the study

Method of measurement

Petersburg Sleep Quality Questionnaire (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: One capsule of Tiryage wabai is taken daily for 30 days one hour before dinner. Raw materials of medicine, prepared from reliable sources. And an initial assessment is made of its quality. Tiryage wabai is prepared by mixing Saffron powders, Aloe vera gel and Myhrr and according to the instructions mentioned in the sources of traditional medicine, including the Tohfat al mo'menin, the Exire A'zam, and Tebe Akbari, and is packaged in the form of capsules. Standardization of the drug is done by measuring total phenol, determining the amount of crocin and alioine, as well as microbial control.

Category

Treatment - Drugs

2

Description

Control group: Take one placebo capsule daily for 30 days one hour before dinner. A suitable placebo is prepared with sufficient similarity and is prepared in similar packages of the drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Avini Comprehensive Health Center

Full name of responsible person

Mina Maarefvand

Street address

Kianmehr, Amir Kabir Boulevard, Azadi Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Hatem Godini

Street address

45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology

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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

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Mina Maarefvand

Position

Non-faculty specialist physician

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

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Position
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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

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

Not applicable

Title and more details about the data/document

Part of the data, such as information about the main consequences, can be shared by inserting it in the study article.

When the data will become available and for how long

Access period starts 8 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data to advance scientific goals

From where data/document is obtainable

Dr. Maarefvand

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

Send the request for information via the announced gmail and the party will receive a response within a maximum of two weeks. dr.m.maarefvand@gmail.com

Comments