

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Study of sleep quality in the elderly and the effect of valerian

Protocol summary

Study aim

Comparison of sleep quality of the elderly before and after receiving valerian

Design

Sixty elderly people who were eligible to enter the study entered the study after obtaining consent and valerian gave them to take two pills with food daily and sleep quality was measured again after one month by the Pittsburgh Questionnaire.

Settings and conduct

Yas Rehabilitation Center All the elderly underwent free clinical examination by the researcher. Eligible individuals completed the Pittsburgh Questionnaire. One month after the intervention, the questionnaire was completed and the sleep quality score was compared before and after the intervention.

Participants/Inclusion and exclusion criteria

60 years old, sleep disorders, no drug allergies, no underlying disease, ability to answer questions

Intervention groups

effect of valerian

Main outcome variables

sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051105N1**

Registration date: **2021-05-02, 1400/02/12**

Registration timing: **retrospective**

Last update: **2021-05-02, 1400/02/12**

Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Ali Davati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7770 9060

Email address

davati@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-01-20, 1395/11/01

Trial completion date

2017-02-19, 1395/12/01

Scientific title

Study of sleep quality in the elderly and the effect of valerian

Public title

Effect of valerian in sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

sleep disorder Ability to answer questions

Exclusion criteria:

History of allergies Drug dependence disease

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Actual sample size reached: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشگاه شاهد

Street address

Persian Gulf highway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2016-04-19, 1395/01/31

Ethics committee reference number

IR-SHAHED.REC.1395.131

Health conditions studied

1

Description of health condition studied

sleep disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality score on the Pittsburgh Questionnaire

Timepoint

One month after starting the study

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Valerian is given in the amount of two tablets (160 mg each tablet) per day to be taken with food.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز جامع توانبخشی سالمندان یاس

Full name of responsible person

خانم دکتر مرضیه شیرازی خواه

Street address

Sattar Khan St.-Bargh Alston

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Province

Tehran

Postal code

1453693611

Phone

+98 21 4428 0429

Email

dr_shirazikhah2002@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

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Tehran

Postal code

3319118651

Phone

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Email

a_davati@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
Shahed University
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
Shahed University
Full name of responsible person
Ali Davati
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Ali Davati
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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable