Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Matricaria chamomilla extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

Protocol summary

Summary

Sleep is one of the basic human needs. Research suggests that sleep quality is diminished with increasing age and the elderly are susceptible to damage caused by poor quality of sleep. Pharmacotherapy for the treatment of sleep disorders, which in many cases may cause adverse effects in the elderly. Research has shown that chamomile extract may be effective on sleep quality. Therefore, in this quasi-experimental clinical trial to determine the effect of MC extract on sleep quality in elderly people admitted to nursing homes takes place, aged 80, after informed consent, are divided into two groups. Intervention group twice daily after lunch and after dinner, chamomile extract 400 mg capsules and the control group received no intervention will be. Sleep quality in elderly people by participating in both pre- and post-intervention questionnaires Pittsburgh Sleep Quality Standard will be measured and will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102015080N1**
Registration date: **2014-05-23, 1393/03/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name

Mehrdad Abdullahzadeh

Name of organization / entity

Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Khorasgan (Isfahan) Branch , Islamic Azad University

Expected recruitment start date

2014-05-14, 1393/02/24

Expected recruitment end date

2014-06-14, 1393/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Matricaria chamomilla extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

Public title

The effect of chamomile on sleep in elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: tend to participate in the study and give consent to do so; having more than 60 years of age; having mental health; the non- occurrence of whatever specific diseases of liver, kidney, asthma, cancer and mental disorders are diagnosed; stay in one of the nursing homes studied; ability to answer questions; lack of sensitivity to chamomile or any of its ingredients; lack of continuous consumption of tea or chamomile extract during the last six months; capability than chamomile

capsules orally; lack of sleep-related illnesses, such as obstructive sleep apnea or restless legs syndrome; the lack of dependence on any drug, analgesics, anti-depressants, sleeping, alcohol and the lack of heparin, warfarin, and aspirin (due to drug interactions with chamomile extract). Exclusion criteria: stopping chamomile by subject, for whatever reason before the end of the intervention period; drug against the patient dose; catching whatever disease during the study period , which led to a ban by the oral administration of MC; indicate any allergic reaction to the MC during the research; lack of willingness to cooperate in the investigation; withdrawal from the study for reasons such as death, illness, or transferred to other centers.

Age
From **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
2014-05-14, 1393/02/24

Ethics committee reference number
23810403922004

Health conditions studied

1

Description of health condition studied
Insomnia

ICD-10 code
G47.0

ICD-10 code description
Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description
Quality of sleep

Timepoint
Pre-intervention and post-intervention

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
Chamomile extract of 400 mg twice daily

Category
Treatment - Drugs

2

Description
No action

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Nursing homes related to IsfahanWelfare

Full name of responsible person

Street address

City
Isfshsn

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran

Full name of responsible person
Dr. payam najafi

Street address
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty