

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial for determining of the effect of Matricaria Chamomile extract on sleep quality in older adults

Protocol summary

Summary

(1) Objectives: Evaluation of the effect of Matricaria Chamomile extract on sleep quality in elderly people, (2) Design: A single blind randomized controlled trial is conducting on sixty elderly adults with inclusion criteria. The subjects will randomly be allocated into two groups of 30, (3) Setting and conduct: Elderly adults with inclusion criteria who refer to the Kahrizak elderly day care charity will randomly allocated into the two groups. A permuted block randomization method is used to allocate the subjects into the two groups, (4) Participants: Elderly adults over the age of 60 years and with a score of 5 and over from the Pittsburgh Sleep Quality Index are recruited into the study, (5) Intervention: the elderly adults in the intervention group will receive two capsules containing 200 mg Matricaria Chamomile extract each day and for four weeks. The control group will receive two capsules containing wheat flour each day and for four weeks, (6) Main outcome measures: The quality of sleep of the subjects will be measured for three consecutive times with two-week intervals.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609023618N5**
Registration date: **2016-11-24, 1395/09/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-24, 1395/09/04

Registrant information

Name

Mohsen Adib-Hajbaghery

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36155540021

Email address

adibhajbagheri_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2016-04-18, 1395/01/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial for determining of the effect of Matricaria Chamomile extract on sleep quality in older adults

Public title

The effect of Matricaria Chamomile extract on sleep quality in older adults

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Age of 60 years and over; Obtaining a score of 5 or greater of the Pittsburgh Sleep Quality Index; Lack of a known mental illness; Lack of known allergies; Lack of continuous or sporadic use of Matricaria Chamomila or its products (as expressed by the patient); Being fully consciousness and ability to answer questions

and give informed consent; Willingness to participate in the study and signing the informed consent; Not taking anticoagulant drugs (Heparin, Warfarin, Aspirin, Plavix); Lack of substance dependence and addiction (to drugs, alcohol, sedatives, antidepressants, hypnotics); Lack of known liver and kidney diseases or asthma, cancer, insulin-dependent diabetes, lupus, heart failure (based on the subjects' health records). Exclusion criteria: Intolerance or reactions to Chamomile while studying; Chamomile withdrawal before the end of the intervention (at least for 3 days); A patient's decision to withdraw from the study; Death; Hospitalization; Transfer to other centers.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ravand Street, Kashan

City

Kashan

Postal code

Approval date

2016-01-05, 1394/10/15

Ethics committee reference number

IR.KAUMS.REC.1394.157

Health conditions studied

1

Description of health condition studied

The effect of Matricaria Chamomile extract on sleep quality in older adults

ICD-10 code

G00-G99

ICD-10 code description

G99.8* Other specified disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

Sleep quality

Timepoint

Pre the intervention, two weeks after the intervention, four weeks after the intervention, six weeks after the intervention

Method of measurement

The score resulted from the Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: Capsules containing 200 mg of Matricaria Chamomile extract, are prescribed twice daily (after lunch and dinner) for four weeks.

Category

Treatment - Drugs

2

Description

In the control group: Capsules containing 200 mg wheat flour, are prescribed twice daily (after lunch and dinner) for four weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kahrizak Charity

Full name of responsible person

Mr Reza Roodgar

Street address

Saheb Al Zaman Stree, Mohammad Shahr, Alborz

City

Mohammad Shahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medical Science Kashan

Full name of responsible person

Doctor Ghulam Ali Hamidi

Street address

Ravand Street, Kashan

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Medical Science Kashan

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

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Seyedeh Nessa Moussavi

Position

Master of Science Student in Geriatric Nursing

Other areas of specialty/work

Street address

Laleh Alley, Golchin 2

City

Sari

Postal code

48137-44181

Phone

+98 11 3322 4854

Fax

Email

Yasamin.Rastgar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Adib-Hajbaghery

Position

PhD in Nursing Education

Other areas of specialty/work

Street address

Ravand Street, Kashan

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

adib44@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Seyedeh Nessa Mousavi

Position

Master of Science Student in Geriatric Nursing

Other areas of specialty/work

Street address

Laleh Alley, Golchin 2

City

sari

Postal code

48137-44181

Phone

+98 11 3322 4854

Fax

Email

Yasamin.Rastgar@yahoo.com

Web page address

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