Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the possible hypnotic impact of Brassica oleracea product in patients with insomnia

Protocol summary

Study aim
Evaluation of the possible hypnotic impact of Brassica oleracea product in patients with insomnia
Design
Randomized clinical trial using cards lottery method, two parallel intervention and control groups, 86 patients (43 people in each group)
Settings and conduct
This clinical trial will be performed on 86 patients aged 18 to 60 who suffer from a sleep disorder. Patients are randomly divided into three groups of 43, the first group receiving 1 capsule of a placebo, and the second group receiving 1 capsule of the extract every day for 4 weeks. The sleep quality of both groups was measured by Pittsburgh standard sleep quality questionnaire before and after the intervention.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient 18 to 60 years old; Sleep problems in recent weeks, with no history of allergic reactions to red cabbage or its derivatives. Exclusion criteria: History of any mental disorder, failure to return for evaluation at the end of the course
Intervention groups
Group 1: recipients of placebo capsules. Group 2: recipients of red cabbage extract capsules.
Main outcome variables
Change of score in the Petersburg Questionnaire before the start of the study and at the end of the study based on the Petersburg Questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190406043175N9**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **prospective**
Last update: **2023-07-09, 1402/04/18**
Update count: **0**
Registration date
2023-07-09, 1402/04/18

Registrant information
Name
fatemeh forouzanfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3761 7318
Email address
forouzanfarf@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-09-23, 1402/07/01
Expected recruitment end date
2026-09-23, 1405/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the possible hypnotic impact of Brassica oleracea product in patients with insomnia

Public title
The effect of red cabbage on insomnia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non-pregnant men and women 18 years or older

Sleeping problem in recent weeks No history of allergic reactions to red cabbage or its derivatives Having enough literacy to read and understand the questionnaire and answer the questions alone

Exclusion criteria:

History of any mental disorder History of serious cardiovascular, liver, kidney or other systemic diseases History of addiction or smoking History of abnormal thyroid function tests History of taking anti-depressant or anti-psychotic drugs two weeks before entering the study Occurrence of allergic reactions to the capsules and their contents during the study period

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The numbers from 1 to 86 are written on 86 papers and placed inside a bag. Even numbers are for intervention group and odd numbers are for control group. Each time a patient enters the study according to entry criteria, a paper is removed from the bag and the number written on the paper is the base of entering to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Healthcare personnel, data collection authorities and those who evaluate the outcome are completely uninformed about the recipient groups. It should be noted that the patient is aware of the clinical trial but does not know whether he is taking the placebo or the main drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Azadi Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.595

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Change of score in the Pittsburgh questionnaire

Timepoint

Before the start of the study and at the end of the study

Method of measurement

Based on the Pittsburgh Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receiving the same form of capsule prepared from red cobbage extract with starch powder without red cobbage in the unique shapes for all groups. It is noteworthy that these capsules are made at the Mashhad Medical Sciences University and at the Pharmacological Research Center of Medicinal Plants. The capsules administrate one dosage every night for 4 weeks. Also, the patient is told to promptly inform the investigators if certain symptoms indicating the side effects of the drug or the sensitivity to the drug.

Category

Treatment - Drugs

2

Description

Intervention group: Receiving the capsule prepared from red cobbage extract with starch powder in form of

unique shapes for all groups. These capsules are made at the Mashhad Medical Sciences University and at the Pharmacological Research Center of Medicinal Plants. The capsules administrate one dosage every night for 4 weeks. Also, the patient is told to promptly inform the investigators if certain symptoms indicating the side effects of the drug or the sensitivity to the drug.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Forouzanfar

Street address
Mashhad University of Medical Science, Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3800 2000

Email
forouzanfarf@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Ghayour-Mobarhan

Street address
Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, University Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 1538

Email
ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Forouzanfar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Mashhad University of Medical Sciences, Azadi square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3800 2538

Email
forouzanfarf@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Forouzanfar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Mashhad University of Medical Sciences, Azadi square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3800 2538

Email
forouzanfarf@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Forouzanfar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Mashhad University of Medical Sciences, Azadi square

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 1538

Email
forouzanfarf@mums.ac.ir

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
Undecided - It is not yet known if there will be 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