

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the effect of licorice plant extract on sleep disorders in women during menopause

Protocol summary

Study aim

Determining the effect of licorice plant extract on sleep disorders in women during menopause

Design

A double-blind RCT with a control group will be conducted on 70 postmenopausal women. Random allocation of samples is done using random block method (18 blocks of 4). The selection of each block will be done randomly by throwing dice for 18 times until the allocation of patients to treatment groups is complete

Settings and conduct

the researcher will refer to the selected health centers affiliated to Qom University of Medical Sciences (each center will be assigned a code and the centers will be selected through a lottery) and will select the eligible people and the women who have a sleep quality score Based on the Pittsburgh Sleep Quality Questionnaire, if it is greater than or equal to 5, they will be randomly allocated into the control or intervention group. The samples and the researchers will be unaware of the content of completely identical envelopes until the last stage of information extraction

Participants/Inclusion and exclusion criteria

Inclusion: Women under 65 years, married, 1 to 3 years have passed since the onset of menopause, BMI between 20-30, Not having an addiction, mental illnesses, death of first-degree relatives in the last year, acute diseases, systemic diseases, taking hormones and antibiotics in the last three months/Exclusion: Reluctance to attend the study, Start treatment with hormonal and sleeping drugs, Allergy to licorice.

Intervention groups

intervention: capsules containing 250mg of licorice root aqueous extract, TDS, for 1 month/placebo: capsules containing 250mg of starch, TDS, for 1 month

Main outcome variables

Sleep quality; sleep duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211207053310N2**

Registration date: **2022-12-24, 1401/10/03**

Registration timing: **prospective**

Last update: **2022-12-24, 1401/10/03**

Update count: **0**

Registration date

2022-12-24, 1401/10/03

Registrant information

Name

Atena Hakimzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 0000 0000

Email address

hakimzadeh.atena@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of licorice plant extract on sleep disorders in women during menopause

Public title

Investigating the effect of licorice on the sleep disorder of postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women under 65 years old married A minimum of one year and a maximum of three years have passed since the onset of menopause Body mass index between 20 and 30 No smoking and no addiction (self and spouse) Not having depression and mental illnesses No death of first-degree relatives in the last year Absence of acute diseases (such as cancer and end stages of organ transplant) No use of hormones and antibiotics in the last three months Absence of systemic diseases (such as kidney disease, blood pressure, blood sugar and blood lipids)

Exclusion criteria:

Reluctance to attend the study Start treatment with hormonal drugs Allergy to licorice Use of cytotoxic drugs and sleeping drugs

Age

To 65 years old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Selected centers: each center is assigned a code and the centers are selected through a lottery. Research unit: Based on block randomization, people are randomly divided into 18 blocks of 4, then each block will be randomly selected by throwing dice for eighteen times (until the allocation of patients to treatment groups is completed).

Blinding (investigator's opinion)

Double blinded

Blinding description

Capsules (licorice and placebo) with the same appearance are placed separately inside the coded envelopes (A web). The participants and clinical researchers will be unaware of the content of A-web envelopes until the final stage of final information extraction.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Qom University of Medical Sciences

Street address

Qom - Shahid Lavasani St. - Qom University of Medical Sciences and Healthcare Services

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2022-11-21, 1401/08/30

Ethics committee reference number

IR.MUQ.REC.1401.192

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

Sleep disorder

ICD-10 code

F51.8

ICD-10 code description

Other sleep disorders not due to a substance or known physiological condition

2**Description of health condition studied**

menopause

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

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

sleep quality

Timepoint

Before the intervention, two weeks after the start of the intervention, one week after stopping the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: consumption of licorice capsules (containing 250 mg of licorice root aqueous extract) 3 times a day for one month.

Category

Treatment - Drugs

2

Description

Control group: consumption of capsules containing 250 mg of starch, 3 times a day for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers covered by Qom University of Medical Sciences

Full name of responsible person

It is not possible to introduce the responsible person until the sampling permit is obtained.

Street address

-

City

Qom

Province

Ghous

Postal code

-

Phone

+98 25 3000 0000

Email

muq@ac.ir

Web page address

http://www.muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

-

Street address

Qom - Shahid Lavasani St. - Qom University of Medical Sciences and Healthcare Services

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Province

Ghous

Postal code

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Phone

+98 25 3000 0000

Email

muq@ac.ir

Web page address

https://www.muq.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghous 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atena Hakimzadeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Shahid Beheshti College of Nursing and Midwifery, in front of Shahid Rajaei Heart Hospital, Valiasr Street, Niayesh Intersection, Tehran

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Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 921 123 3571

Email

hakimzadeh.atena@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Mousavi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Atena Hakimzadeh

Position

Master Student

Latest degree

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Other areas of specialty/work

Midwifery

Street address

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City

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Province

Tehran

Postal code

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Phone

+98 921 123 3571

Email

hakimzadeh.atena@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants' information remains confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Informed consent will be obtained from the samples. The
final report will be presented in the form of an article.

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Researchers and those interested in the subject of
research

Under which criteria data/document could be used

Do not tamper with the data

From where data/document is obtainable

Send request by email or call

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

Send requested items about a week after request

Comments