

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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		Secondary Ids	empty
Public title	Investigating the effect of licorice on the sleep disorder of postmenopausal women	Ethics committees	
Purpose	Treatment	<u>1</u>	
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	Ethics committee	
Age	To 65 years old	Name of ethics committee	Research Ethics Committees of Qom University of Medical Sciences
Gender	Female	Street address	Qom - Shahid Lavasani St. - Qom University of Medical Sciences and Healthcare Services
Phase	3	City	Qom
Groups that have been masked	- Participant - Care provider - Investigator	Province	Ghoum
Sample size	Target sample size: 70	Postal code	3713649373
Randomization (investigator's opinion)	Randomized	Approval date	2022-11-21, 1401/08/30
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).	Ethics committee reference number	IR.MUQ.REC.1401.192
Blinding (investigator's opinion)	Double blinded	Health conditions studied	
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.	<u>1</u>	
Placebo	Used	Description of health condition studied	Sleep disorder
Assignment	Parallel	ICD-10 code	F51.8
Other design features		ICD-10 code description	Other sleep disorders not due to a substance or known physiological condition
		<u>2</u>	
		Description of health condition studied	menopause
		ICD-10 code	N95
		ICD-10 code description	Menopausal and other perimenopausal disorders
		Primary outcomes	
		<u>1</u>	
		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

Ghoum

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

Ghoum University of Medical Sciences

Full name of responsible person

-

Street address

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

City

Qom

Province

Ghoum

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

Ghoum 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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Province

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1985717443

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Mousavi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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Shahid Beheshti College of Nursing and Midwifery, in front of Shahid Rajaei Heart Hospital, Valiasr Street, Niayesh Intersection, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

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