Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 on70postmenopausal 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 containing250mg of licorice root aqueous extract, TDS, for1month/placebo:capsules containing250mg of starch, TDS, for1month

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

Ghoum

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