

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of effectiveness of lemon Balm and chamomile on sleep disorders in menopausal women

Protocol summary

Study aim

Comparison of lemon Balm and chamomile on sleep disorders of menopausal women

Design

This study is a triple-blind clinical trial. subjects will be selected by convenience sampling method then they will be randomly assigned to one of the groups. study will be conducted on 110 postmenopausal 50-60 years old women. intervention includes taking lemon balm capsule in one group and chamomile capsule in other group for one month. one month after starting medication, Pittsburgh Sleep Quality Index will be completed by subjects and finally, data will be analyzed using statistical tests.

Settings and conduct

The study will be conducted on 110 postmenopausal 50-60 years old women referred to Arak health centers. intervention includes taking lemon balm capsule (250 mg extract of lemon balm) in one group and chamomile capsule (400 mg extract of Chamomile) in other group for one month and twice a day.

Participants/Inclusion and exclusion criteria

Mild and moderate sleep disorder based on Pittsburgh Sleep Quality Questionnaire, lack of physical and mental illness affecting sleep, not taking drugs that affect sleep quality. Unpredictably significant change in sleep conditions including travelling

Intervention groups

Consumption of lemon balm in group 1 and chamomile in group 2

Main outcome variables

sleep hygiene

General information

Reason for update

To correct title spelling mistake

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073110076N5**

Registration date: **2015-09-04, 1394/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-05, 1398/08/14**

Update count: **1**

Registration date

2015-09-04, 1394/06/13

Registrant information

Name

Maryam Saeedi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1417 3524

Email address

m.saeedi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Arak University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

2015-08-23, 1394/06/01

Actual recruitment end date

2015-12-22, 1394/10/01

Trial completion date

2015-12-22, 1394/10/01

Scientific title

Comparison of effectiveness of lemon Balm and chamomile on sleep disorders in menopausal women

Public title

Comparison of Lemon Balm and chamomile effect on sleep disorders in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

menopause women Mild and moderate sleep disorder based on Pittsburgh Sleep Quality Questionnaire lack of physical and mental illness affecting sleep not taking drugs that affect sleep quality

Exclusion criteria:

Unpredictably significant change in sleep conditions Including travelling, relocation

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **110**

Actual sample size reached: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected by convenience sampling and were randomly divided into intervention and control groups using random number table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Subjects, researcher and data analyser were blinded

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Arak University Of Medical Sciences

Street address

Vice Chancellor for research of Arak University of Medical Sciences, Arak

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2015-06-29, 1394/04/08

Ethics committee reference number

IR.ARAKMU.REC.1394.78

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

Seep disorder

ICD-10 code

G47

ICD-10 code description

Other sleep disorders

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

sleep disorder

Timepoint

after study and one month after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups**1****Description**

" Intervention group1": Consumption of lemon balm capsules(capsules Containing 250 mg extract of lemon balm twice a day) in one of group for one month

Category

Treatment - Drugs

2**Description**

"Intervention group 2": Consumption of Chamomile capsules(capsules containing 400 mg extract of Chamomile twice a day) in other group for one month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health centers in Arak

Full name of responsible person

Zeinab Alizadeh

Street address

Arak

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Fax

+98 86 3313 3147

Email

zeinab_alizadeh88@yahoo.com

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Zeinab Alizadeh

Position

MSC in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing&Midwifery Faculty, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+86 34173503

Fax**Email**

zeinab_alizadeh88@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Arak University of Medical Sciences

Full name of responsible person

Dr Ghazavi

Street address

Department Of research&Technology, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Email

zeinab_alizadeh88@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Arak 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University Of Medical Sciences

Full name of responsible person

Zeinab Alizadeh

Position

MSc in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing&Midwifery faculty, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3503

Fax**Email**

zeinab_alizadeh88@yahoo.com

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

Arak University Of Medical Sciences

Full name of responsible person

Zeinab Alizadeh

Position

MSc in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing&Midwifery Faculty, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3503

Fax

Email

zeinab_alizadeh88@yahoo.com

Web page address

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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments