

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Evaluation of the effectiveness of Melissa Officinalis L. nasal drop on the quality of sleep in pregnant women

Protocol summary

Study aim

Determination and comparison between and within groups of the average sleep duration, sleep adequacy index, time to fall asleep, and quality of sleep in the intervention and control groups before and after the intervention

Design

The study's method will be a double-blind, randomized controlled clinical trial, with a simple random sampling method. The total sample size, will be 100 persons. Permutation blocks method will be used for random assignment of treatment type.

Settings and conduct

At first, relevant permits and an informed consent form will be obtained. In order to collect data, the demographic profile questionnaire and Pittsburgh sleep quality questionnaire will be used. Mothers with mild to moderate sleep disorders will be included in the study. The method of blinding is double-blind, and the researcher is not aware of the contents of the drops, and only the person's name is entered in the randomization table based on the code that the person has, and the oils are provided to patients by one of the pharmacy colleagues. patients will be re-examined in the 4th and 8th weeks after starting to use the drug. The way to take the medicine is to use one drop of the drug in each nostril twice in the morning and at night. In case of complications or problems, they will be removed from the study. The information of the project will be kept completely confidential.

Participants/Inclusion and exclusion criteria

Pregnant women who suffer from sleep disorders and don't mention any past medical history. In case of any past medical history, they will not be included in the study

Intervention groups

Pregnant women who receive lemon balm drops and those who receive neutral drops

Main outcome variables

Improving daily performance; reducing mother's fatigue; increasing family well-being; reducing anxiety; improving immune system, Hypothalamus, Pituitary and Adrenal function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231213060353N1**

Registration date: **2024-02-27, 1402/12/08**

Registration timing: **retrospective**

Last update: **2024-02-27, 1402/12/08**

Update count: **0**

Registration date

2024-02-27, 1402/12/08

Registrant information

Name

Negin Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5507 0589

Email address

rastegariz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-02-03, 1402/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Melissa Officinalis L. nasal drop on the quality of sleep in pregnant women

Public title

Evaluation of the effectiveness of Melissa Officinalis L. nasal drop on the quality of sleep in pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Gestational age of 28-34 weeks after obtaining informed consent Mother's first pregnancy (mother's nulligravidity) Suffering from mild and moderate sleep disorder by self-report and according to the Pittsburgh Questionnaire Ability to answer questionnaire questions Not using complementary medicine during the previous three months No dependence or addiction to alcohol, drugs, tobacco and medicines Not having family problems No history of any respiratory allergy Not having a history of allergy to Lemon balm or cross-reaction with the mint family as self-reported

Exclusion criteria:

Taking drugs that affect the sleep-wake cycle The presence of any problems in the pregnancy process Suffering from depression or anxiety (self-reported and the need to take medication) Suffering from any psychological factor interfering with sleep disorders Suffering from kidney diseases, heart failure, respiratory disorders and sleep-wake cycle diseases such as espiratory apnea and restless leg syndrome. Showing any allergic reaction to lemon balm oil continuous consumption (twice or more per week) of Lemongrass tea or extract during the last month having problems related to airway and nasal obstruction and Sinusitis

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, all study groups will contain equal sample size, which can be used by limited randomization. The method that is used in this study, will be permuted block randomization . In this method, the size of all blocks will be equal and 10 blocks of 10 will be selected by the "Random software allocation" software, which is capable

of generating a random sequence using the permutation block method. The randomization unit in this study will be an individual unit.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding is double-blind, and the researcher is not aware of the contents of the drops, and only the person's name is entered in the randomization table based on the code that the person has. The oils whose content is unknown and only have A and B labels, are given to patients by one of the pharmacy colleagues.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

No. 39, Joahari Naad Ave., Shir Mohamadi St. , Nazi Abad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1811619833

Approval date

2023-09-09, 1402/06/18

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.106

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

Sleep quality of pregnant women in the third trimester

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Percentage of pregnant women who have sleep disorders

Timepoint

Registration of Pittsburgh sleep quality questionnaire at the beginning of the study (before the start of the

intervention) and 4 and 8 weeks after starting the use of Lemon balm oil drops

Method of measurement

Pittsburgh sleep quality questionnaire

Secondary outcomes

1

Description

Sleep quality score

Timepoint

At the beginning of the study and 4 and 8 weeks after the beginning of Lemon balm oil drops

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Intervention groups

1

Description

Intervention group: pregnant women suffering from sleep disorders referring to the pregnancy clinic of Mahdিয়ে Hospital: a prepared and approved sample of Melissa Officinalis will be poured into a standard amount of neutral oil and then a standard amount of sterile water will be added to it. then It will be expoused to indirect heat so the water will completely be evaporated, and finally, the remaining plant will be filtered from the oil so the final product of lemongrass plant oil will be derived from it. The method of using neutral oil (placebo) and lemon balm oil (intervention) is to drip one drop of the respective oil in each nostril twice a day . The medication will be consumed for 8 weeks. The drops will be made by the Faculty of Traditional Medicine of Tehran University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: pregnant women suffering from sleep disorders referring to pregnancy clinic of Mahdিয়ে Hospital who receive neutral oil. neutral oil is an oil that has no effect in the treatment of sleep disorder and its preparation is industrial and contains liquid Paraffin. The drops will be made by the Faculty of Traditional Medicine of Tehran University of Medical Sciences.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdিয়ে hospital

Full name of responsible person

Athena Behforouz

Street address

Rajab Nia St., Shishgarkhane St., Fedaiyan Islam St., Shush Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

+98 21 5506 2627

Email

mahdিয়ে_hospital@sbmu.ac.ir

Web page address

<https://mmc.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohamad Hashem Hashempur

Street address

7th Floor, Central building of Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3212 2430

Fax

+98 71 3235 6996

Email

vcrdep@sums.ac.ir

Web page address

<https://research.sums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rastegari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Fatemeh (P.B.U.H) School of nursing and midwifery,
Namazi hospital, Namazi square, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

rategariz@sums.ac0ir

Email

rategariz@sums.ac0ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rastegari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Fatemeh (P.B.U.H) School of nursing and midwifery,
Namazi hospital, Namazi square, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

rategariz@sums.ac0ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rastegari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Fatemeh (P.B.U.H) School of nursing and midwifery,
Namazi hospital, Namazi square, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

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