Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 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

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Iran (Islamic Republic of)

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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
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Tehran
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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 Mahdiyeh 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 Mahdiyeh 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

Mahdiyeh hospital

Full name of responsible person

Athena Behforouz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohamad Hashem Hashempur

Street address

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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

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Other areas of specialty/work
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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