Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Inhalation of Melissa officinalis (lemon balm) essential oil on fatigue and sleep quality of mothers of premature infants in the neonatal intensive care unit

Protocol summary

Summary

This clinical trial study will be conducted to evaluate the effect of inhalation of Melissa officinalis essential oil on fatigue and sleep quality of mothers with premature infants in the neonatal intensive care unit. From mothers with premature infants from 28 to 32 weeks admitted in the Ommolbanin and Imam Reza Hospitals of Mashhad as research community will be invited. The sample size is 25 people in each group who are divided randomly With a draw of packets number one to two into test and control groups. Inclusion criteria are mother's presence within 48 hours after delivery in the department; fetal age of 28-32 weeks; no physical and mental illness; lack of olfactory disorder; no addiction mother to all drugs and psychosis; mothers do not use sedative medications, relaxation and sleep medicine and Sleep disturbances (Pittsburgh Sleep Quality Index 5 or more) and the exclusion criteria are mother's unwillingness in trial for any reason; have an allergic history of herbal medicines; depression; Infant death. This intervention involves inhaled mask dipped in 5 to 7 drops of Melissa officinalis essential oil 1.5% for 20-30 minutes twice daily for two weeks. The main variables of fatigue and maternal sleep quality are evaluated by two Visual Scale of Fatigue Measurement and Pittsburgh Sleep Quality Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012532190N1**
Registration date: **2017-11-19, 1396/08/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

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Masoume Sinaei

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Mashhad University of Medical Sciences

Expected recruitment start date
2017-07-06, 1396/04/15

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Inhalation of Melissa officinalis (lemon balm) essential oil on fatigue and sleep quality of mothers of premature infants in the neonatal intensive care unit

Public title

The effect of Inhalation of Melissa officinalis (lemon balm) essential oil on fatigue and sleep quality of mothers of premature infants in the neonatal intensive

care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Mother's informed consent to participate in the intervention; Mother's presence within 48 hours after delivery in the department; Fetal age of 28-32 weeks; No physical and mental illness; Lack of olfactory disorder; no addiction to all drugs and psychosis; Mothers do not use sedative medications, Relaxation and sleep medicine; Sleep disturbances (Pittsburgh Sleep Quality Index 5 or more). Exclusion criteria: Mother's unwillingness in the trial for any reason; Have an allergic history of herbal medicines; Depression (Depression Scale of Edinburgh 13 or more); Infant death.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Qaryashi Building, Central Organization of the University, Daneshgah Street

City

Mashhad

Postal code

13944-91388

Approval date

2017-07-02, 1396/04/11

Ethics committee reference number

IR.MUMS.REC.1396.99

Health conditions studied

1

Description of health condition studied

sleep

ICD-10 code

G47

ICD-10 code description

Sleep disorders

2

Description of health condition studied

fatigue

ICD-10 code

R53

ICD-10 code description

Malaise and fatigue

Primary outcomes

1

Description

fatigue

Timepoint

Before the intervention, one week after the intervention and two weeks after the intervention

Method of measurement

Visual Scale of Fatigue Measurement

2

Description

sleep quality

Timepoint

Before the intervention, one week after the intervention and two weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality Scale

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: Control group: There is no intervention for mothers in this group.

Category

Other

2

Description

Group2: Intervention group: Inhaled mask dipped in 5 to 7 drops of lemon balm essential oil 1.5% for 20-30 minutes twice daily for two weeks.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Masoume Sinaei
Street address
Imam Reza Hospital, Ebne Sina Street
City
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2

Recruitment center
Name of recruitment center
Ommol Banin Hospital
Full name of responsible person
Masoume Sinaei
Street address
Ommol Banin Hospital, Ayatullah Behjat Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Qaryashi Building, Central Organization of the University, Daneshgah Street
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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
Vice chancellor for research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty