

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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

2017-11-19, 1396/08/28

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

Registrant information

Name

Masoume Sinaei

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

sinaeim2@mums.ac.ir

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

empty

Recruitment centers1**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

Mashhad

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

City

Mashhad

Sponsors / Funding sources1**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

City

Mashhad

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****Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Masoume Sinaei

Position

Master's student of Neonatal Care Nursing

Other areas of specialty/work**Street address**

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Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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Fax**Email**

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Web page address**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