Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Lavender cream with or without foot bath during pregnancy and postpartum on sleep quality and anxiety: a randomized controlled trial

Protocol summary

Summary

This trial aims to assess the effect of Lavender cream with or without foot bathduring pregnancy and postpartum on sleep quality and anxiety (primary outcomes) and on depression, stress, fatigue, mother to infant bonding, length of gestation and birth weight (secondary outcomes). 129 women in 25-28 weeks of pregnancy will be allocated into three groups (receiving lavender and footbath, only lavender or only placebo cream) using block randomization with block sizes of 3, 6 and 9 andallocation ratio 1:1:1. A person not involved in sampling and data collection will put the creamsinto sequentially numbered sealed opaque packs to conceal allocation sequence.All subjects will rub the creams on their feet once a day an hour before bedtime.In the first group, the pack will also contain a paper written footbath on it. This group will immerse legs into 40 to 42°c water for 10-20 minutes after using cream. The subjects will discontinue using the creams after 8 weeks and restart it from the first day until 6 weeks postpartum. Footbath would be used with no discontinuation. All subjects will fill Pittsburgh Sleep Quality Index (PSQI) and the Distress, Anxiety and Stress Scale (DASS-21) at 4 and 8 weeks and Multidimensional Assessment of Fatigue (MAF) at 6 weeks after intervention; all the questionnaires at baseline and 6 weeks after delivery, and Postpartum Bonding Questionnaire (PBQ) 6 weeks after delivery. Repeated Measurement and ANCOVA will be used to compare mean score of the outcome variables among the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211293706N17**
Registration date: **2014-04-04, 1393/01/15**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-04-04, 1393/01/15

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences (all funds, except the creams), Barij Essence Pharmaceutical company (producing and packing the Lavender and Placebo creams)

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Lavender cream with or without foot bath during pregnancy and postpartum on sleep quality and anxiety: a randomized controlled trial

Public title

Effect of Lavender cream with or without foot bath during

pregnancy and postpartum on sleep quality and anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: • First to third pregnancy • Gestational age of 25 to 28 weeks • Having a singleton live fetus • Literate • Aged 18 to 45 years • Acquiring Pittsburgh Sleep Quality Index score of 5 or higher. Exclusion criteria: • Having any chronic disease (including diabetes, thyroid disease, preeclampsia, anemia) • Using certain medications • Smoking • History of infertility • Unwanted pregnancy • Allergy to the herbs • Any wounds on the washing and cream rubbing site • Having severe anxiety, depression or stress (Anxiety score above 10, depression score above 14 or stress score above 17 in the DASS-21) • Obesity (BMI above 29) • Having night shift work • No access to phone line.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **129**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Triple blind only about the intervention II and control groups but not blinded about the interventiongroup III

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research deputy, Tabriz University of Medical Sciences

Street address

3rd floor, 2nd central building, Golgasht street, Tabriz, Iran

City

Tabriz

Postal code

Approval date

2013-01-21, 1391/11/02

Ethics committee reference number

91184

Health conditions studied

1

Description of health condition studied

sleep quality in pregnancy AND postparetum

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

2

Description of health condition studied

Anxiety in pregnancy and postpartum

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Sleep quality score

Timepoint

Before intervention, 4 and 8 weeks after initiation of intervention and 6 weeks after delivery

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Anxiety score

Timepoint

At baseline, 4 and 8 weeks after initiation of intervention and 6 weeks after delivery

Method of measurement

DASS-21

Secondary outcomes

1

Description

Length of gestation

Timepoint

After delivery

Method of measurement

Using the LMP or resulu of Ultrasound done before 12 weeks of pregnancy and birth date

2

Description

Birth weight

Timepoint

After delivery

Method of measurement
Weight recorded in the newborn discharge card

3

Description
Fatigue Score
Timepoint
At baseline, 6 weeks after intervention and 6 weeks after delivery
Method of measurement
Multidimensional Assesment o Fatigue scale (MAF)

4

Description
Score of Stress
Timepoint
At baseline, 4 and 8 weeks after intervention and 6 weeks after delivery
Method of measurement
DASS-21

5

Description
Score of Depression
Timepoint
At baseline, 4 and 8 weeks after intervention and 6 weeks after delivery
Method of measurement
DASS-21

6

Description
Score of mother and infant bonding
Timepoint
Six weeks after delivery
Method of measurement
Postpartum Bonding Questionnaire (PBQ)

Intervention groups

1

Description
Intervention groupI: The participants will rub Lavender creamon their feet once a day about 1 hour before bedtime for the first 8 weeks, as well as for 6 weeks postpartum; they will also immerse legs in 40 to 42 °c water to a depth of 5 cm above the ankle for 10-20 minutes for 8 weeks and will be recommended to continue it until 6 weeks postpartum, if they like.
Category
Treatment - Drugs

2

Description
Intervention groupII: The participants will rub Lavender cream on their feet once a day about an hour before bedtime for the first 8 weeks, as well as for 6 weeks postpartum.
Category
Treatment - Drugs

3

Description
Control group: The participants will get no intervention but will get routine care and instructions like the other groups
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Selected public health centers and health posts in Tabriz
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz university of medical sciences
Full name of responsible person
Dr. Kazem Shakouri
Street address
Golgasht st.
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tabriz university of medical sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity

Barij Essence Pharmaceutical Company

Full name of responsible person
Dr. Mohsen Tagizadeh

Street address
Mashade Ardehal- Kashan- PO.Box 1178

City
Kashan

Grant name

Grant code / Reference number

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

Title of funding source
Barij Essence Pharmaceutical Company

Proportion provided by this source

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
Faculty of Nursing & Midwifery- Tabriz University of Medical Sciences

Full name of responsible person
Fatemeh Effati Daryani

Position
MSc student in midwifery

Other areas of specialty/work

Street address
Kousar Dormitory, South Shariati Ave, Tabriz, Iran

City
Tabriz

Postal code

Phone
+98 44 1225 2309

Fax

Email
mahta0608@yahoo.com , effati_f@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person
Sakineh Mohammad-Alizadeh-Charandabi

Position
Assistant professor, PhD in Reproductive Health

Other areas of specialty/work

Street address
Midwifery Department, Faculty of Nursing and Midwifery,South Shariati, Tabriz, Post Code: 5138947977, P.O.Box: 51745-347

City
Tabriz

Postal code

Phone
+98 41 1477 2699

Fax
+98 41 1479 6969

Email
alizades@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

Full name of responsible person
Sakineh Mohammad-Alizadeh-Charandabi

Position
Associate professor, PhD in Reproductive Health

Other areas of specialty/work

Street address
Midwifery Department, Faculty of Nursing and Midwifery,South Shariati, Tabriz, Post Code: 5138947977, P.O.Box: 51745-347

City
Tabriz

Postal code

Phone
+98 41 1477 2699

Fax
+98 41 1479 6969

Email
alizades@tbzmed.ac.ir

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