

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 bath during 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 and allocation ratio 1:1:1. A person not involved in sampling and data collection will put the cream into 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

91184

## 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 intervention group 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

## Health conditions studied

### 1

#### Description of health condition studied

sleep quality in pregnancy AND postpartum

#### 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 Assessment of 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 cream on 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**

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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

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**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

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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*