

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison study of the effects of peppermint tablet and lavender essential oil on the anxiety level of the first stage of labor in nulliparous women

#### Protocol summary

##### Summary

The aim of study is to comparison the effect of Peppermint tablet and Lavender essential oil on the level of anxiety in the first stage of labor in nulliparous women. Therefore, according to inclusion and exclusion criteria of the study, eligible parturient women will be selected. The sample size is 50 subjects in each group, which randomly stratified in three groups of peppermint tablets, essential oil of lavender and control group. Then in the group that receiving peppermint tablet, to each of the mothers in the two period's (cervical dilatation 5 to 6 cm and cervical dilatation 7 to 9 cm), Two Peppermints tablets construction pharmaceutical company Dinah will be given. at the same times for second group one Cloth soaked in a drop of lavender oil will be given. For control group routine care will be done. For all the groups before and fifteen minutes after intervention, Manifest Anxiety Scale Spielberger will be completed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015043022022N1**  
Registration date: **2017-04-21, 1396/02/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-21, 1396/02/01

##### Registrant information

###### Name

Leila Hashemi Nasab

###### Name of organization / entity

Kurdistan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3356 4907

##### Email address

hash.lyla@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kurdistan University of Medical Sciences

##### Expected recruitment start date

2017-03-30, 1396/01/10

##### Expected recruitment end date

2017-04-30, 1396/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison study of the effects of peppermint tablet and lavender essential oil on the anxiety level of the first stage of labor in nulliparous women

##### Public title

Maternal anxiety during labor and delivery

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

(Inclusion criteria: Primiparous women; Gestational age term (37 to 42 weeks); Candidate for a vaginal birth; Singleton; cervical dilatation of at least 4 cm; A live fetus; Spontaneous onset of labor; cephalic presentation; Estimated fetal weight ranging from 2500 grams to 4000 grams. (Exclusion criteria: Use of sedatives in the past 8 hours; Substance abuse; Lack of medical diseases;

mental disorders; Use any herbal remedy during the last 48 hours; Complications of pregnancy (Preeclampsia, Premature rupture of membranes more than 12 hours before Admitting mother, Placental abruption, Placenta previa, Polyhydramnios, Oligohydramnios, abnormal bleeding); History of any systemic diseases (Diabetes, High blood pressure, Heart disease, Kidney, Etc.); Sensitivity to peppermint; Mother decided to discontinue study; Fetal tachycardia; Fetal bradycardia or late deceleration; Disposal of meconium; Dysfunction in labor progress according to the labor Partograph protocol of Ministry of Health); Recent death of a family member.

**Age**

No age limit

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kurdistan University of Medical Sciences

**Street address**

In front of Shadi Hotel, Pasdaran street, Kurdistan University of Medical Sciences

**City**

Sanandaj

**Postal code**

0098876617713446

**Approval date**

2016-08-13, 1395/05/23

**Ethics committee reference number**

IR.MUK.REC.1395.116

**Health conditions studied****1****Description of health condition studied**

Maternal distress during labour and delivery

**ICD-10 code**

O75.9

**ICD-10 code description**

Complication of labour and delivery, unspecified

**Primary outcomes****1****Description**

Labor anxiety

**Timepoint**

Evaluation of labor anxiety in parturient women after giving peppermint tablets and cloth soaked in a drop of lavender essential oil and control group in dilatations of 5-6 cm and 7-9 cm

**Method of measurement**

Manifest Anxiety Scale Spielberger

**Secondary outcomes****1****Description**

Comparison of labor anxiety in parturient after giving peppermint tablet, lavender essential oil and control group

**Timepoint**

cervical dilatation of 5-6 cm and 7-9 cm

**Method of measurement**

Manifest Anxiety Scale Spielberger

**Intervention groups****1****Description**

The first intervention: giving one cloth soaked in a drop of lavender essential oil to parturient women in dilatation of 5-6 cm and 7-9 cm dilatation

**Category**

Prevention

**2****Description**

The second intervention: giving a peppermint tablets to parturient women in the dilation of 5-6 cm and 7-9 cm dilatation

**Category**

Prevention

**3****Description**

The third intervention groups: Perform routine care for parturient women in control group at dilatation of 5-9 cm

**Category**

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Beasat Hospital, Maternity Ward

**Full name of responsible person**

08733285910

**Street address**

In front of Mullah Burhanuddin Ali School, keshavarz street, Beasat Hospital

**City**

Sanandaj

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kurdistan Medical University Of Sciences

**Full name of responsible person**

Farzin Razaee

**Street address**

In front of Shadi Hotel, Pasadaran street, Kurdistan Medical University of Sciences

**City**

Sandajan

**Grant name**

بودجه عمومی

**Grant code / Reference number**

muk.rec

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

Yes

**Title of funding source**

Kurdistan Medical University Of 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**

Kurdistan Medical University of Sciences

**Full name of responsible person**

Leila Hashemi Nasab

**Position**

Lecturer of Kurdistan Medical University of Sciences

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

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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Rozhin Mohammadi

**Position**

BSc Midwifery Student of Kurdistan Medical University of Sciences

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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*