

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

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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

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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