Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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, Polyhydroamnious, Oligohydramnious, 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan Medical University Of Sciences
Full name of responsible person
Farzin Razaee
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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

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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