Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of lavender aromatherapy on anxiety of primiparous women during first stage of labor

Protocol summary

Summary

Aim of this study is to determine the effect of lavender aromatherapy on anxiety of primiparous women during first stage of labor. This study is an interventionl study in two groups (exam and control group) with pre-test and post-test. Study population are pregnant women referred to the physiologic delivery center in Fatemieh hospital in Hamadan city. A sample of 35 people in the intervention group and 35 people in the control group has been determined. The samples will be selected randomly with six blocks (ABBABA) method. Then, the researcher will measure state and trait anxiety by Spielberger questionnaire in two groups (intervention and control groups) . Researcher will be poured a drop of lavender oil with concentration of 2% (under the supervision of pharmacist) on fabric napkins. Napkins will attach with pin to patient' dress collar. Then they will be requested to be breath normally for 15 minutes.The questioner will be measure state and trait anxiety for three times 15, 60 and 90 minutes after intervention. Finally two groups will be compared on anxiety during first stage of labor using descriptive and inferential statistics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072310426N12**
Registration date: **2016-07-28, 1395/05/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-28, 1395/05/07

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lavender aromatherapy on anxiety of primiparous women during first stage of labor

Public title

The effect of lavender aromatherapy on anxiety of primiparous women during first stage of labor In Fatemieh Hospital Hamadan city

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: mothers'age between 18-35 years; Single fetus pregnancy; Gestational age 42-37 weeks; Cervical dilation between 5-3 cm; Lack of obstetric complications in pregnancy; important medical disorders ; and no history of psychological problems. Exclusion

criteria: The incidence of allergy symptoms in the mother; Precipitate delivery; cesarean section.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences- ShahidFahmideh Street- Counterpoint of Mardom Park

City
Hamadan

Postal code
65178

Approval date
2016-05-14, 1395/02/25

Ethics committee reference number
IR.UMSHA.REC.1395.83

Health conditions studied

1

Description of health condition studied
Aromatherapy with lavender on anxiety in labor ; Pregnancy-related condition, unspecified

ICD-10 code
O75.9

ICD-10 code description
Complication of labour and delivery, unspecified

Primary outcomes

1

Description
State and trait anxiety

Timepoint
15, 60 and 90 minutes after the intervention

Method of measurement
Standard Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group: After obtaining written testimonial from people, The samples will be selected by randomization blocks with six blocks (ABABA) method to two experimental and control groups. Lavender essential oil produced from BarijEsanse company will give to mothers in the intervention. Researcher will be poured a drop of lavender oil with concentration of 2% (under the supervision of pharmacist) on fabric napkins. Napkins attach with pin to dress collar, Then Will be requested from mother breathing normally for 15 minutes. Researcher will be measured and recorded apparent and hidden anxiety in the experimental group before and after 15, 60 and 90 minutes after the intervention by Spielberger State and Trait questionnaire (STAI).

Category
Treatment - Drugs

2

Description
In control group: Mothers in the control group to be delivered placebo (water) in a bottle as same as intervention group . Research assistant will be poured a drop of placebo (water) on fabric napkins for mothers in the control group. Napkins attach with pin to dress collar, Then Will be requested from mother to breathing normally for 15 minutes. Researcher will be measured and recorded apparent and hidden anxiety in the experimental group before and after 15, 60 and 90 minutes after the intervention by Spielberger State and Trait questionnaire (STAI).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemih Hospital

Full name of responsible person

Mahtab Satari
Street address
Shahid Zamani, Fatemih Hospital
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
ShahidFahmideh Street- Counterpoint of MardomParkHamadan University of Medical Sciences
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan University of Medical 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
Hamadan University of Medical Sciences
Full name of responsible person
Dr. Parisa Parsa
Position
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Person responsible for updating data

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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