

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the Effect of Aromatherapy with Geranium Essence on Anxiety and Labor pain in Nulliparous Women

Protocol summary

Study aim

To determine the effect of aromatherapy with aromatic geranium (geranium) on the anxiety and labor pain of primiparous women

Design

The clinical trial has a control group, double-blind, randomized, on 100 patients, and SPSS 22 statistical software will be used for data analysis.

Settings and conduct

Place of execution: Imam Jafar Sadiq (AS) maternity hospital, Aligudarz city, Lorestan province. Aromatherapy starts from the dilation of 4-5 cm and the intensity of pain and anxiety are measured and recorded before and 20 minutes after aromatherapy; Then the aromatherapy is repeated every 20 minutes until the end of delivery. The intensity of anxiety will be measured in dilatations of 4 to 5 and 8 to 10 cm and the intensity of pain in dilatations of 4 to 5, 6 to 7 and 8 to 10 cm. In this study, neither the researcher responsible for data entry into the software and data analysis, nor the researcher (using a nose clip during the intervention) will be aware of the allocation of patients to the experimental or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian race and first birth; singleton pregnancy with an age of 37 to 42 weeks; Mother's age is 18-35 years; Dilatation 4-5 cm at the time of entering labor. Exclusion criteria: fetal distress or labor progress disorder; existence of medical and obstetrical problems in the current pregnancy; Incidence of sensitivity to geranium essential oil in a person during study; use of pain reliever or anti-anxiety medication at least 3 hours before the intervention

Intervention groups

In the aromatherapy group, 2 drops of geranium essential oil soaked in gas, and in the control group, 2 drops of distilled water soaked in gas are attached to the collar of the samples and the administration will be repeated every 20 minutes.

Main outcome variables

Labor pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091021002618N3**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Aromatherapy with Geranium Essence on Anxiety and Labor pain in Nulliparous Women

Public title
Evaluation of the effect of Aromatherapy with Geranium on Anxiety and Labor pain

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Iranian race and being a firstborn Single pregnancy with age 37 to 42 weeks Mother's age is 18-35 years
 Dilatation 4-5 cm at the beginning of labor Having at least 2-3 spontaneous uterine contractions lasting 40-45 seconds within 10 minutes The regularity of the fetal heartbeat with a number of 110-160 beats per minute
 The mother's vital signs are normal The number of fetal movements is normal according to the mother's report
 Body mass index 20-30 kg/m² Height more than 145 cm
 The estimated weight of the fetus is 2500-4000 grams
 The fit of the fetal head with the mother's pelvis based on clinical examination Proportion of uterine height with gestational age in clinical examination
Exclusion criteria:
 Fetal distress or disruption of labor progress Existence of medical and midwifery problems in the current pregnancy
 Incidence of sensitivity to geranium essential oil in a person during the study The presence of olfactory disorders, allergies or previous unpleasant experiences with certain scents
 The use of painkillers or anti-anxiety drugs at least 3 hours before the intervention
 Addiction to tobacco, drugs and alcohol and the need to receive them
 The existence of any obstacle to perform natural childbirth
 The need to strengthen labor with oxytocin or other methods
 The need for an emergency caesarean section
 The need to use other medicinal and non-medicinal pain reduction methods
 Facing an important and unfortunate incident during the last week

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

Gender
Female

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method is accessible and based on the study entry criteria. In this way, after obtaining written consent from the samples, people are assigned to 2

intervention and control groups using block random allocation method and blocks of 4. By using this method, it can be ensured that an equal number of participants enter the intervention and control groups in consecutive time intervals. Entry of people into each of the groups is done according to the number of selected blocks and the arrangement inside the block. In order to prevent the possibility of the effect of the aroma spread in the air on the people of the studied groups, the department manager will be requested to place the studied samples in a separate room based on randomization and the same type of intervention received. For blocks of 4, six modes are considered as follows, and the said blocks will be used approximately 4 times (24 people are allocated each time) so that the final sample size is allocated to two treatment and intervention groups: 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)

Double blinded

Blinding description

This research will be double-blind in such a way that neither the researcher responsible for data entry into the software and data analysis nor the researcher (using a nose clip during the intervention) will be aware of the allocation of patients to the experimental or control group; Also, due to the possibility of the release of essential oil molecules in the environment, the release of pleasant odors (scented sprays) and sometimes the windows being open, we place the patients in separate LDR rooms and avoid opening the windows during the intervention; We also ask the hospital services to postpone the cleaning of the room, which is done using detergent solutions and may have an unpleasant smell, to before or after the intervention. The data will be collected by the researcher and the research assistant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Headquarters of Lorestan University of Medical Sciences, Anoushirvan Rezaei Square, Moalem St.

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Province

Lorestan

Postal code

8197978133

Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.LUMS.REC.1402.110

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

Anxiety and labor pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety intensity score in Spielberger Anxiety Questionnaire

Timepoint

The intensity of anxiety will be measured before aromatherapy and in dilations of 4 to 5 and 8 to 10 cm.

Method of measurement

Spielberger anxiety questionnaire

2**Description**

Labor pain intensity score on visual analog grade scale

Timepoint

Pain intensity will be measured before aromatherapy and at 4 to 5, 6 to 7 and 8 to 10 cm dilations.

Method of measurement

Visual analog degree scale

Secondary outcomes

empty

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

Intervention group: In the aromatherapy group, 2 drops (0.13 cc) of geranium essential oil are soaked in gauze and attached to the collar of the samples, and the administration will be repeated every 20 minutes. The intensity of anxiety will be measured in dilations of 4 to 5 and 8 to 10 cm and the intensity of pain in dilations of 4 to 5, 6 to 7 and 8 to 10 cm.

Category

Treatment - Drugs

2**Description**

Control group: In the control group, 2 drops (0.13 cc) of distilled water are soaked in gauze and attached to the collar of the samples, and the administration will be

repeated every 20 minutes. The intensity of anxiety will be measured in dilations of 4 to 5 and 8 to 10 cm and the intensity of pain in dilations of 4 to 5, 6 to 7 and 8 to 10 cm.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam jafar sadegh hospital

Full name of responsible person

Hanieh Hafizi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Lorestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available