Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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.

City

Khorram abad

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 dilatations.
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 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.
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 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.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam jafar sadegh hospital
Full name of responsible person
Hanieh Hafizi
Street address
Imam Jafar Sadiq (AS) Hospital, Razi Square, East Modares Street, East Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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pr.lums@yahoo.com
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

Lorestan University of Medical Sciences

Full name of responsible person

Soheila Pirdade Biranvand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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