Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of aromatherapy with clove essential oil on anxiety and Post cesarean section pain

Protocol summary

Study aim
Determining the effect of aromatherapy with clove essential oil on anxiety and pain after caesarean section in women admitted to Taleghani Hospital, Ilam.

Design
Clinical trial with control group, without blinding, randomized on 72 patients

Settings and conduct
In this randomized clinical trial, the number of 72 women who have Inclusion criteria are divided into two intervention and control groups. Inclusion criteria include: age 18-49 years, spontaneous pregnancy, low-risk pregnancy, olfactory health, women under spinal anesthesia, live birth with Apgar 7 and above, elective cesarean section (of predetermined), less than 3 pregnancies, less than 3 deliveries, gestational age between 37-42 weeks. Exclusion criteria include: allergy to cloves, feeling uncomfortable with the smell of essential oil during the study, possible annoying side effects, history of respiratory problems and migraines, emergency caesarean section, general anesthesia, any type of medical problem, history of mental disorders before and during pregnancy, history of previous surgery on the uterus, The duration of cesarean section is extended to more than one hour. 3 hours after leaving the operating room, related questionnaires will be completed and pain and anxiety scores will be measured. Then the intervention will be done at 4, 8 and 12 hours after cesarean section by inhaling 3 drops of clove essential oil on a cotton swab at a distance of ten centimeters from the nose for 10 minutes. Half an hour after each intervention, the level of pain and anxiety will be measured.

Participants/Inclusion and exclusion criteria
The research community of this study will be women aged 18-49 who undergo cesarean surgery in Taleghani Hospital in Ilam city in 1402

Intervention groups
Aromatherapy group with clove scent Aromatherapy group with normal saline

Main outcome variables
Pain, Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101218005415N3**
Registration date: **2024-01-03, 1402/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-03, 1402/10/13**
Update count: **0**

Registration date
2024-01-03, 1402/10/13

Registrant information

Name
fatemeh janani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 3312 0140

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janani.f@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-31, 1402/10/10

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of aromatherapy with clove essential oil on anxiety and Post cesarean section pain

Public title

Investigating the effect of aromatherapy with clove essential oil on anxiety and Post cesarean section pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being a volunteer to participate in the study Age 18-49 years Spontaneous pregnancy Low risk pregnancy Olfactory health women under spinal anesthesia live birth with Apgar 7 and above Elective cesarean section (predetermined) Frequency of pregnancy less than 4 Birth frequency less than 3 Gestational age 37 to 42 weeks

Exclusion criteria:

Reluctance to participate in the study Allergy to cloves History of respiratory problems and migraines History of mental disorders (depression) before and during pregnancy History of liver and kidney problems (essential oils are excreted through liver, kidney and exhalation) History of previous surgery on the uterus (other than caesarean section) Suffering from high blood pressure Suffering from migraines Suffering from autoimmune and inflammatory diseases Performing other surgery with caesarean section

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of samples into groups is done using Block Randomization method. In order to equalize the history of previous cesarean section and the level of anxiety before the intervention in the study groups, first there are classes as having a history of cesarean section / no history of cesarean section and low (20-30) / moderate (31-42) / severe (<43) anxiety, (6 classes) create and then the co-epidemiologist of the project determines the allocation of people to the study groups using the blockrand R software package and makes it available to the research team so that the people are placed in the groups based on the order of entry and belonging to each class be studied in a balanced way.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and the data analyst will not know the type of intervention for the study groups.

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

Kamalvand road

City

Khoram Abad

Province

Lorestan

Postal code

6814993165

Approval date

2023-12-09, 1402/09/18

Ethics committee reference number

IR.LUMS.REC.1402.292

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

2

Description of health condition studied

Anxiety

ICD-10 code

F48

ICD-10 code description

Other nonpsychotic mental disorders

Primary outcomes

1

Description

Pain, Anxiety

Timepoint

4,8,12 hours after cesarean

Method of measurement

Visual Analogue Scale, Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aromatherapy group with clove essential oil

Category

Treatment - Other

2

Description

Control group: Aromatherapy group with normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Kimiya Radmanesh

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Shahid Beheshti Blvd, Ilam town, Iran

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Sponsors / Funding sources

1

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Name of organization / entity

Khoram-Abad University of Medical Sciences

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available