

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of chamomile aromatherapy with and without oxygen on severity of pain, bloating and nausea in women after cesarean section with spinal anesthesia.

Protocol summary

Study aim

The effect of chamomile aromatherapy with and without oxygen on the severity of pain, bloating and nausea in women after cesarean section with spinal anesthesia

Design

The study was a clinical trial with control group performed on 136 women who underwent cesarean section and randomly assigned to 3 intervention groups and one control group.

Settings and conduct

136 women undergoing cesarean section were randomly assigned to three intervention groups and one control group. The data collection tool was visual analogue scale completed by the researcher 6, 12, 18 hours after cesarean section

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of middle ear disease, no preeclampsia or eclampsia. No smoking or alcohol. No history of chamomile allergies. No history of olfactory problems. Cesarean section should be performed with spinal anesthesia Change the anesthesia method
Exclusion criteria: Perform cesarean section other than cesarean section. Ill get ill and require more or less than the prescribed oxygen level. Patient needs intensive care

Intervention groups

.Intervention group received chamomile Essence oil with simple mask and small nebulizer, second group oxygenated with simple mask alone, third group received aromatherapy with nebulizer alone and control group received no intervention

Main outcome variables

Pain, bloating, nausea

General information

Reason for update

At the beginning of the study, changes were made in the

intervention times and measurement times. These changes were recorded

Acronym

IRCT registration information

IRCT registration number: **IRCT20141222020401N7**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-15, 1401/09/24**

Update count: **2**

Registration date

2020-01-05, 1398/10/15

Registrant information

Name

Nazafarin Hosseini

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3323 5144

Email address

hosseini.nazafarin@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2020-01-05, 1398/10/15

Actual recruitment end date

2020-03-18, 1398/12/28

Trial completion date

2020-03-19, 1398/12/29

Scientific title

The effect of chamomile aromatherapy with and without oxygen on severity of pain, bloating and nausea in women after cesarean section with spinal anesthesia.

Public title

The effect of chamomile aromatherapy with and without oxygen on severity of pain, bloating and nausea in women after cesarean section with spinal anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

no history of middle ear disease, preeclampsia or eclampsia, asthma and other acute and chronic diseases
No smoking or alcohol drinking
No history of allergy to chamomile
No history of olfactory problems
Cesarean section should be performed with spinal anesthesia

Exclusion criteria:

Change the anesthesia method
Other than cesarean section
The patient needs special care

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **136**

Actual sample size reached: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomized block allocation method with standard 4-person blocks was used and the subjects were divided into 3 intervention groups and one control group, with labels A, B, C, D on four sheets and and oxygen interventions. Aromatherapy, oxygen therapy, aromatherapy and control were also written on four separate sheets, and a colleague who was unaware of this was asked to randomly remove a label for each intervention. In this way we had four random groups and four factorial twenty-four blocks. The size of each block was four and their order was different. Then the blocks were randomly assigned by placement and the patients were sorted. Each block of patients was assigned randomly.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the smell of chamomile, it was not possible to blind the researcher and participants, but the analyst has no information about the type of intervention related to each data.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Assistance of Research and Technology of the University , Yasouj University of Medical Sciences , Shahid Motahari Blvd., Yasuj , Iran

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591741417

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.YUMS.REC.1398.036

Health conditions studied

1

Description of health condition studied

pain, nausea and distention of women in post Cesarean section with spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

bloating

Timepoint

6 hours after cesarean section, 12 hours after cesarean section, 18hours after cesarean section

Method of measurement

visual analog scale

2

Description

pain

Timepoint

6 hours after cesarean section, 12 hours after cesarean section, 18 hours after cesarean section

Method of measurement

visual analog scale

3

Description

nausea

Timepoint

6 hours after cesarean section, 12 hours after cesarean section, 18 hours after cesarean section

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention of chamomile aromatherapy with oxygen (chamomile essential oil from Zardband Company) is given to patients about the general purpose of the research and informed consent is obtained from them and their spouse. Training on collecting these samples is required to collect information and a baseline questionnaire including demographic and morphometric information is collected. On the day that is selected as intervention day 1, patients in the intervention group will be rubbed with a patch test on a wrist (patch test) and covered with a cloth for 2 minutes to determine if they are allergic. Delete the study. In this intervention group, a drop of chamomile essential oil plus distilled water is poured into a small nebulizer that attaches to the facial mask and adjusts to 6 liters per minute (28), which is a drop of essential oil when entering the women's ward. Chamomile with distilled water is poured into a small nebulizer attached to the face mask and oxygen is adjusted for 6 liters per minute (delay test (At 6, 6.30 and 7 hours after the operation, the mask is applied to the patient's face for 5 minutes each time. 5-12 liters per minute with a simple mask can deliver 35-50% oxygen to the patient

Category

Prevention

2

Description

Dual Oxygen Intervention alone, Double Intervention at the same time will receive 6 liters of oxygen per minute with simple face mask without aromatherapy chamomile

Category

Prevention

3

Description

Intervention group: Intervention third chamomile aromatherapy alone, Intervention group three will receive chamomile aromatherapy at the same time after sensitization test with oxygen nebulizer

Category

Prevention

4

Description

The control group did not receive oxygen and aromatherapy chamomile.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Yasuj Hospital

Full name of responsible person

Nazafarin Hosseini

Street address

Nursing school , Dr. Shahid Jalil street, Yasouj , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Vice-chancellor of Research, Dr. Hossein Mari Oryad

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Vice chancellor of Research and Technology, Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj , Iran

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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

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Nazafarin Hosseini

Position

PhD in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Hajar Zamani Habibabad

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable