Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of lemon essential oil on the severity of nausea and vomiting during caesarean delivery under spinal anesthesia

Protocol summary

Study aim
To determination the effect of lemon essential oil on the severity of nausea and vomiting during caesarean delivery under spinal anesthesia

Design
This is a controlled clinical trial with parallel groups, single blind, randomized using the block randomization method.

Settings and conduct
After random assignment into two groups, the demographic questionnaire is completed. Fifteen minutes before surgery, physiological variables and nausea and vomiting are recorded. In Group A, three drops of lemon essence are applied to a 10×10 cm gauze pad and attached to the patient's collar for 15-20 minutes of inhalation. In Group B, three drops of an odorless, color-matched liquid (water + essence color) are attached similarly. Physiological indices and nausea and vomiting intensity are recorded. This study is conducted at Hakim Hospital, Neyshabur.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 18-45 years, elective surgery, no history of severe pregnancy-related nausea, complete fasting time, no use of anti-nausea medication before surgery. Exclusion Criteria: History of allergy to lemon, history of gastrointestinal diseases, need for general anesthesia, need for reoperation.

Intervention groups
In the intervention group (A), 15 minutes before surgery, three drops of lemon essence will be applied using a dropper onto a 10×10 cm gauze pad from Barij Kashan company. This pad will be attached to the patient's collar, and the patient will be instructed to inhale normally for 15-20 minutes. In control group (B), three drops of a color-matched, odorless liquid (water + essence color) similar to the lemon essence used in Group A will be applied to a 10×10 cm gauze pad, attached to the patient's collar, with the instruction to inhale normally for 15-20 minutes.

Main outcome variables
Severity of nausea and vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160825029520N7**
Registration date: **2024-12-01, 1403/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-01, 1403/09/11**
Update count: **0**

Registration date
2024-12-01, 1403/09/11

Registrant information

Name
kiana babaei

Name of organization / entity
tarbiat modares university

Country
Iran (Islamic Republic of)

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+98 44010724

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k.babaei@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lemon essential oil on the severity of nausea and vomiting during caesarean delivery under spinal anesthesia

Public title

Effect of lemon essential oil on the severity of nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18-45 years old Elective surgery Not history of severe nausea and vomiting during pregnancy Complete NPO time Not taking anti-nausea medication before surgery

Exclusion criteria:

History of allergy to lemon History of gastrointestinal diseases Need for general anesthesia Need for reoperation

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **143**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign individuals to two groups and ensure balanced group sizes, block randomization with block sizes of 4 will be used. Participants will be randomly allocated to Group A (lemon essence group) and Group B (distilled water group).

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the data analyst will be blinded to the group allocations (Group A with lemon essence and Group B with distilled water).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Neyshabur University of Medical Sciences

Street address

Pardis Neyshabour University of Medical Sciences

City

Neyshabour

Province

Razavi Khorasan

Postal code

14139-93186

Approval date

2024-10-29, 1403/08/08

Ethics committee reference number

IR.NUMS.REC.1403.048

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Severity of Nausea and Vomiting

Timepoint

15 minutes before surgery/ after spinal/ before surgery/ after the umbilical cord clamp/ after surgery/ entering the recovery

Method of measurement

Bellville Nausea and Vomiting scoring scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

15 minutes before surgery/ after spinal/ before surgery/ after the umbilical cord clamp/ after surgery/ entering the recovery

Method of measurement

Anesthesia monitoring

2

Description

Heart rate

Timepoint

15 minutes before surgery/ after spinal/ before surgery/

after the umbilical cord clamp/ after surgery/ entering the recovery

Method of measurement

Anesthesia monitoring

3

Description

Saturation of peripheral oxygen

Timepoint

15 minutes before surgery/ after spinal/ before surgery/ after the umbilical cord clamp/ after surgery/ entering the recovery

Method of measurement

Anesthesia monitoring

Intervention groups

1

Description

In the intervention group, 15 minutes before surgery, three drops of lemon essence (Barij Kashan) are placed on a 10×10 sterile gauze using a dropper, attached to the patient's collar, and the patient is instructed to inhale it naturally for 15-20 minutes.

Category

Treatment - Drugs

2

Description

In the control group, three drops of a color-matched odorless liquid (water + lemon essence dye) are placed on a 10×10 sterile gauze, attached to the patient's collar, and the patient is instructed to inhale it naturally for 15-20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim hospital

Full name of responsible person

Seyedeh maryam Seyedi

Street address

Bagh rud Rd, Hakim Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

Ali Gholami

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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

Neyshabour 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

Neyshabour University of Medical Sciences

Full name of responsible person

Kiana Babaei

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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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
No more information

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
Not applicable

Data Dictionary
Not applicable