

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Cardamoms Inhalation Aromatherapy on the Mothers' Nausea and Vomiting in Peri & Post-Operation of the Elective Cesarean Section

Protocol summary

Summary

A single blind randomized, controlled trial will be conducted to determine the effects of Cardamoms inhalation aromatherapy on the mothers' nausea and vomiting in peri & post-operation of the elective Cesarean section. 70 eligible mothers will be randomly allocated to the placebo group (n=35) or experimental group (n=35). Inclusion criteria: Having 16-48 years old; Literacy; Singleton and normal infants; Elective operation through Spinal anesthesia; Nausea after starting spinal anesthesia. Exclusion criterion: both mother and fetus poor conditions. All eligible subjects will be trained about the three deep breathes of bags (inhalation for 3 seconds and exhalation for 7 seconds) and evaluating their nausea severity on VAS(0-100 mm). The two 2" x 2" gas-Pad will be moistened with 2 ml of distilled water without (Placebo group) or with 2 drops of essential oil of cardamom (Experimental group) put in the zipper plastic bags. During surgery, after mother's nausea, the onset nausea severity based on the VAS will be recorded. Then, the mothers in the experimental group will be asked to breathe deeply three times of the oil of cardamom soaked pads and the mothers in the placebo group will be asked to breathe deeply three times of the distilled water soaked pads. Again, two minutes later, the same breathing patterns will be repeated in both groups. The severity of subjects' nausea based on the VAS will be measured and recorded after five minutes. The frequency of their retching and vomiting during surgery, recovery and two hours after the operation will be assessed in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050333794N1**

Registration date: **2017-06-05, 1396/03/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-05, 1396/03/15

Registrant information

Name

Masumeh Mirzaiee

Name of organization / entity

Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Cardamoms Inhalation Aromatherapy on the Mothers' Nausea and Vomiting in Peri & Post-Operation of the Elective Cesarean Section

Public title

Cardamom aromatherapy on the women's nausea and vomiting in Cesarean Section operation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Mothers with 16-48 years old; Literacy; Singleton and normal infants; Elective Cesarean section operation through Spinal anesthesia; Nausea after starting spinal anesthesia; Lack of nausea due to the underlying disease (Gastrointestinal and kidney diseases) or during the third trimester of pregnancy; A healthy olfactory sense; No history of asthma and respiratory distress due to cardiopulmonary diseases; No allergies to herbal essences and Cardamom; No taking antiemetic or emetic medications or herbal medications during past twenty-four hours; and no opioid addiction and tobacco using. Exclusion criterion: Mothers with an inappropriate process of caesarean section operation (both mother and fetus poor conditions); More than twice spinal needle insertions or use of general anesthesia follow it; An inability to determine the severity of nausea according to VAS despite training; Vomiting or retching during the research intervention.

Age

From **16 years** old to **48 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

City

Hamadan

Postal code

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.UMSHA.REC.1396.91

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.9

ICD-10 code description

O82.9 Delivery by caesarean section, unspecified

Primary outcomes

1

Description

The severity of nausea of mothers' peri- & post-operation of the Cesarean Section

Timepoint

Before the intervention (initial measurement), 5 minutes after intervention, Post-Operation: in the recovery room and 2 hours after operation

Method of measurement

Visual Analogue Scale (VAS 0-100)

Secondary outcomes

1

Description

Frequency of vomiting

Timepoint

during surgery, in the recovery room and 2 hours after operation

Method of measurement

Frequency

2

Description

Frequency of retching

Timepoint

during surgery, in the recovery room and 2 hours after operation

Method of measurement

Frequency

Intervention groups

1

Description

The two 2 "x 2" gas-Pad will be moistened with 2 ml of distilled water put in the zipper plastic bags in a separate room every day. During surgery after mother's expressing nausea, the onset nausea severity based on the VAS will be recorded. Then, the mothers will be

asked to breathe deeply three times of the distilled water soaked pads. Again, two minutes later, the same breathing patterns will be repeated. The severity of subjects' nausea based on the VAS will be measured and recorded after five minutes. The frequency of their retching and vomiting during surgery, recovery and two hours after the operation will be assessed in both groups.

Category

Placebo

2

Description

The two 2 "x 2" gas-Pad will be moistened with 2 ml of distilled water with 2 drops of essential oil of cardamom put in the zipper plastic bags in a separate room every day. During surgery after mother's expressing nausea, the onset nausea severity based on the VAS will be recorded. Then, the mothers will be asked to breathe deeply three times of the oil of cardamom soaked pads. Again, two minutes later, the same breathing patterns will be repeated. The severity of subjects' nausea based on the VAS will be measured and recorded after five minutes. The frequency of their retching and vomiting during surgery, recovery and two hours after the operation will be assessed in both groups.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr hospital Malayer

Full name of responsible person

Akbar Fazeli

Street address

Malayer, Iran nabovat

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

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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

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan, University of Medical Sciences, Nursing & Midwifery School, Medical-Surgical Nursing Depart

Full name of responsible person

Zahra Khalili

Position

Master of Science, Faculty Member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Mahnaz Khatiban

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Ph.D. in Nursing

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty