Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Compare the effectiveness of essential oils of chamomile or placebo on intensity and quality of pain after cesarean section

Protocol summary

Summary

Study is double blind clinical trial comparative study of inhalation of chamomile essense versus plasebo on post operative pain reliefe in cesarean surgery.128 women, referred to mashhad Imam Reza Hospital operating room for cesarean surgery randomly devide into 2 groups.Inclusion criteria: The same type of anesthesia (spinal anesthesia) and anesthetic used; 38 to 42 weeks of gestational age; Nulli parous. exclusion criteria:Reluctance to continue participating in the exercises; Use powerful hypnotics or analgesics drugs; Having allergy and breathing problems; History of warfarin they will undergo spinal anesthesia and cesarean section will be performed.When the post-operative pain starts, and 4, 8, and 12 hours after that, patients will undergo aromatherapy using chamomile essence. patient’s pain score is measured using VAS and quality of pain is measured using McGill questionnaire. then ipatients in the case group will be requested to breathe over a piece of cotton containing 1 drops of the 5 % chamomile essence oil from a distance of 5 cm for 10-20 minutes, then the pain score will be measured again.If the score is > 4, 100 mg of IM Diclofenac will be prescribed.In control group the same procedures will be performed, but instead of the chamomile essence, 1 drops of placebo will be used. The heart rate, blood pressure, nausea, vomiting, dizziness and satisfaction will be recorded before and after the aromatherapy according to the questionnaire. After starting an IV line, patients will be given 500 ml of ringer solution. Then, they will undergo spinal anesthesia

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016042427558N1**
Registration date: **2016-10-09, 1395/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-09, 1395/07/18

Registrant information

Name

Ameneh Basiri

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 4401 1004

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basiria2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effectiveness of essential oils of chamomile or placebo on intensity and quality of pain after cesarean section

Public title

The effect of chamomile Essense on Cesarean post operative pain relief

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Consent for participation in the study; Ability to speake Farsi The same type of anesthesia (spinal anesthesia) and anesthetic used; 38 to 42 weeks of gestational age; Nulli parous. exclusion criteria:Reluctance to continue participating in the exercises; Use powerful hypnotics or analgesics drugs; Having allergy and breathing problems; History of warfarin

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar University of Medical Sciences

Street address
School of Nursing and Midwifery; Next to the Police Station to SHahroud road, Sabzevar

City
Sabzevar

Postal code

Approval date
2015-03-09, 1393/12/18

Ethics committee reference number
Medsab.Rec.93.123

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52.0

ICD-10 code description
Acute pain

Primary outcomes

1

Description
Pain Intensity

Timepoint
befor of aromatherapy and after 20 minute

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Pain Quality

Timepoint
befor of aromatherapy and after 20 minute

Method of measurement
Modify Short Form McGill Pain Questionnaire

Intervention groups

1

Description
In the intervention group 1 drop essential oil of chamomile 5% on the pad (small gas) dropped and the patient is asked at a distance of 5 cm from nose to breathe for 20-15 minutes and then again on the half hour pain intensity using tools McGill pain questionnaire measuring visual short in the control group was given a placebo

Category
Placebo

2

Description
1 drop of placebo-treated control group on gas and at a distance of 5 cm from the nose and breathe for 15-20 minutes.And then the intensity and quality of pain was measured using the tools mentioned questionnaire.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of Education, Research and Treatment of Imam Reza

Full name of responsible person
Roqiyeh Zardosht

Street address
Shariati square - Mashhad - Khorasan Razavi

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Moosa Reza Tadayonfar

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School of Nursing and Midwifery; Next to the Police Station to SHahroud road, Sabzevar

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Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
Ameneh Basiri

Position
Master Student Critical Care Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Roqiyeh Zardosht

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Position
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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