Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison of the Effect of Lavender Essence and Chamomile Essence on pain severity after cesarean section under spinal anesthesia: A blind placebo-controlled randomized clinical trial.

Protocol summary

Summary

This study is conducted in order to compare the influence of Lavender Essence and Chamomile Essence on pain severity after cesarean section under general anesthesia. The study is a blind placebo-controlled randomized clinical trial. It would be done in Phase II clinical trials and single-center. The study population is cesarean section candidates in Besat Hospital in Sanandaj. Based on inclusion criteria, reduction samples probability and Purposeful sampling, 129 participants are selected; Then based on drawing a sealed envelopes from number one to three for each patient, the samples are allocated into three groups. Inclusion criteria included; surgical candidates; volunteered to participate in the study; lack of underlying chronic medical conditions; under spinal anesthetic with a specific drug, Get hundred mg diclofenac suppository in the recovery room, having more than three in the visual analog scale pain after surgery. Exclusion criteria included Patient's withdrawal from the research, and unpredicted events after surgery such as cardiac arrest or patient's death. As having pain more than 3 scales; In the first intervention group, two drops of lavender essence and In the second intervention group, two drops of Chamomile essence is poured on a cotton swab. In the control group, Two drops of placebo (normal saline) is poured on cotton swabs and the patient is asked to inhale it. Pain is measured by a second researcher. second researcher as pain scale evaluator is blind to placebo and kinds of interventions. Based on Visual Analog Scale (VAS); severity of pain is recorded from zero to ten. Demographic information, Severity of pain and uage of analgesics after intervention are recorded in the information sheet.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016081726861N2**
Registration date: **2016-09-27, 1395/07/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-27, 1395/07/06

Registrant information

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Name of organization / entity
Kurdistan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

Expected recruitment start date

2016-02-04, 1394/11/15

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Effect of Lavender Essence and Chamomile Essence on pain severity after cesarean section under spinal anesthesia: A blind placebo-controlled randomized clinical trial.

Public title

The Comparison of the Effect of Lavender Essence and Chamomile Essence on pain severity after cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included: Cesarean section candidates (after surgery); being volunteer to participate in the study; lack of underlying medical conditions (diabetes, chronic respiratory disease, chronic heart disease, kidney or liver disorders and other acute or chronic disorders); surgery under spinal anesthesia; Get 100-mg diclofenac suppository in the recovery room; getting more than three scores of pain severity using the visual analog scale after surgery. Exclusion criteria included Patient’s unwillingness from continuing the study, and unpredicted events after surgery such as cardiac arrest or patient’s death.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **129**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random allocation is based on using the draw without placing a sealed envelope which contain number one, two or three. There are 129 sealed envelopes including 43 sealed envelopes contains number one for lavender essence group; 43 sealed envelopes contains number two for chamomile essence group and 43 sealed envelopes contains number three for placebo group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Pasdaran street, Sanandaj, postal code:13446-66177

City

Sanandaj

Postal code

13446-66177

Approval date

2015-07-11, 1394/04/20

Ethics committee reference number

IR.MUK.REC.94.122

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

N94

ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

Pain

Timepoint

As having pain more than 3 scales; from discharging recovery till 6 hours after surgery

Method of measurement

Based on Visual Analog Scale (VAS); severity of pain is recorded from zero to ten

Secondary outcomes

1

Description

the rate of consumption of analgesic

Timepoint

after the intervention

Method of measurement

Based on the frequency of use and dose of medication in information sheet

Intervention groups

1

Description
Intervention group1: in the case of having pain more than 3 scales; from discharging recovery till 6 hours after surgery; two drops of lavender essence are poured on a ball of cotton and the patient is asked to inhale it. The intervention will be done just one time and the medical analgesics will be ordered If pain persists.
Category
Treatment - Drugs

2

Description
Intervention group2: in the case of having pain more than 3 scales; from discharging recovery till 6 hours after surgery; two drops of Chamomile essence are poured on a ball of cotton and the patient is asked to inhale it. The intervention will be done just one time and the medical analgesics will be ordered If pain persists.
Category
Treatment - Drugs

3

Description
Placebo group: in the case of having pain more than 3 scales; from discharging recovery till 6 hours after surgery; two drops of normal saline are poured on a ball of cotton and the patient is asked to inhale it. The intervention will be done just one time and the medical analgesics will be ordered If pain persists.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Bbaharreh Najafi
Street address
Besat Hospital, Keshavarz Street, Sanandaj
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research and technology of Kurdistan University of Medical Sciences
Full name of responsible person
Farzin Rezaee
Street address
Vice Chancellor for research and technology of Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj, code:66177-13446
City
Sanandaj
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 Kurdistan 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
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Person responsible for scientific inquiries

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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