

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Name

Jamal Seidi

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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

Name of organization / entity

Kurdistan University of medical sciences

Full name of responsible person

Baharreh Najafi

Position

Nurse/MS.C

Other areas of specialty/work

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Besat Hospital, Keshavarz Street, Sanandaj

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6619616776

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Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Jamal Siedi

Position

Ph.D, Assistant professor

Other areas of specialty/work

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

Kurdistan University of Medical Sciences

Full name of responsible person

Jamal Seidi

Position

ph.D/Assistant professor

Other areas of specialty/work**Street address**

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

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