

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of effect of the local infiltration of bupivacain with or without dexamethasone on severity of acute pain in women undergoing cesarian section

Protocol summary

Study aim

The effect of topical bupivacaine injection with or without topical dexamethasone on the severity of acute pain in women undergoing cesarean section referred to Mahzad Hospital in Urmia

Design

The third phase of a double-blind randomized clinical trial with parallel groups in 75 pregnant women candidates for elective cesarean section with fanstyle incision, which will be divided into three groups of 25 people using a random number table taken from www.graphpad.

Settings and conduct

After obtaining informed consent and recording initial information including age, medical history, history of previous pregnancies and previous deliveries, gestational age of patients taking drugs or alcohol, smoking, hookah and weight, all patients under spinal anesthesia with 12 mg bupivacaine 5 / 0% will be placed. The patient and the transfusion surgeon will not be aware of the patient group and the injectable drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria include 1- Pregnant women in the age range of 18 to 40 years 2- Women who are in the ASA1 and ASA2 groups according to the ASA (American Society of Anesthesiologists) in terms of physical condition. Exclusion criteria include 1- Long surgery longer than two hours 2- History of allergy to local anesthetic 3- History of cesarean section more than twice 4- History of drug abuse 5- History of fibromyalgia or chronic nerve pain 6- High BMI 35 7- Changing the type of surgery.

Intervention groups

first group, 10 cc of marcaine 0.5% plus 10 cc of normal saline IM the second group 10 cc of marcaine 0.5% plus 8 cc of normal saline with 2 cc of dexamethasone IM control group 8 cc of normal saline IM

Main outcome variables

All patients will be evaluated for pain intensity at zero

hour of admission to recovery, based on VAS score, Adult nonverbal pain scale, and this criterion will be recorded and compared for the three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220501054713N1**

Registration date: **2022-05-22, 1401/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-22, 1401/03/01**

Update count: **0**

Registration date

2022-05-22, 1401/03/01

Registrant information

Name

Farnaz Alizadeh

Name of organization / entity

Country

Germany

Phone

+49 4133 379269

Email address

ayatollahi.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of the local infiltration of bupivacain with or without dexamethasone on severity of acute pain in women undergoing cesarian section

Public title

Evaluation of effect of the local infiltration of bupivacain with or without dexamethasone on severity of acute pain in women undergoing cesarian section

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Pregnant women in the age range of 18 to 40 years 2- Women who are in ASA1 and ASA2 groups according to ASA (American Society of Anesthesiologists) in terms of physical condition.

Exclusion criteria:

Long surgery longer than two hours History of allergy to local anesthetics History of cesarean section more than twice History of drug abuse History of fibromyalgia or chronic nerve pain BMI above 35 Change the type of surgery.

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **75****Randomization (investigator's opinion)**

Randomized

Randomization description

75 pregnant women who are candidates for elective cesarean section will be examined by Fanstyle incision, which will be divided into three groups of 25 people using a random number table taken from www.graphpad.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient groups will be coded and this coding will be blurred for researchers, patients and outcome assessors and data analysts and clinicians, and only patient names will be kept in a package after grouping and coding. And the appearance of the drugs and placebo will be chosen quite similar to each other.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

G3QJ+GPV, Urmia, West Azerbaijan Province

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.UMSU.REC.1401.036

Health conditions studied**1****Description of health condition studied**

Pain from cesarean section

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes**1****Description**

Visual Analogue Scale Score after cesarean section

Timepoint

VAS score after cesarean section at zero hours of recovery and one hour after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Dosage of the drug in the first 24 hours after cesarean section

Timepoint

the first 24 hours after cesarean section

Method of measurement

Total dose of drugs used per mg/dl

Intervention groups

1

Description

Intervention group: Intervention group 1: The first procedure will inject 0.5 cc of marcaine 0.5% plus 10 cc of normal saline into the fascia and subcutaneous muscle.

Category

Treatment - Drugs

2

Description

Intervention group: The second group of 10 cc of marcaine 0.5% plus 8 cc of normal saline with 2 cc of dexamethasone ampoule will be injected into the fascia and subcutaneous muscle.

Category

Treatment - Drugs

3

Description

Control group: 8 cc of normal saline will be injected into the fascia and subcutaneous muscle.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahzad Hospital of Urmia

Full name of responsible person

Farnaz Alizadeh Hoshyar

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dralizadehfarnaz@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology

Street address

G3QJ+GPV, Urmia, West Azerbaijan Province

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hayatollahi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Haleh Ayatollahi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data file and encrypted information will be shared via personal email without the patients's name, if there is a reasonable request from the researchers.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For systematic review studies or meta-analysis

From where data/document is obtainable

Send email to Dr. Haleh Ayatollahi with the address hayatollahi@yahoo.com

What processes are involved for a request to access data/document

By sending an email and a detailed explanation of the reason for the request and the requested items

Comments