Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

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

Public title
Evaluation of effect of the local infltration 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.
Age
From **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 size
Target 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
Street address
G3QJ+GPV, Urmia, West Azerbaijan Province
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3223 4897
Email
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
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3223 4897
Email
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
Street address
G3QJ+GPV, Urmia, West Azerbaijan Province
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
hayatollahi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Haleh Ayatollahi

Position
Professor

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+98 44 3223 4897

Email
hayatollahi@yahoo.com

Person responsible for updating data

Contact

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Oroumia University of Medical Sciences

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hayatollahi@yahoo.com

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