

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the Effect of Subcutaneous Dexamethasone Added to Bupivacaine on Postcesarean Pain Relief

Protocol summary

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Summary

The objective of this study was to assess the effect of subcutaneous Dexamethasone added to Bupivacaine on post cesarean pain control. 75 pregnant women were randomly assigned to receive following interventions at the time of skin closure, A) Bupivacaine 20 ml, 0.25% (SC) + Dexamethasone 4 ml (16 mg) (SC) + Normal saline 4 ml iv B) Bupivacaine 20 ml, 0.25%(SC) + Dexamethasone 4 ml (16 mg) IV + Normal saline 4 ml iv C) Bupivacaine 20 ml, 0.25% (SC) + normal saline 4 ml SC + normal saline 4 ml IV (placebo group). Pain intensity, systolic and diastolic blood pressure, heart rate and opioid consumption were evaluated at the recovery room, 6, 12, 24, 48 and 72 hours postoperatively.

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2008-07-29, 1387/05/08

Expected recruitment end date

2009-10-10, 1388/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809242405N3**

Registration date: **2010-01-20, 1388/10/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-01-20, 1388/10/30

Registrant information

Name

Mitra Jabalameli

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

Scientific title

Evaluating the Effect of Subcutaneous Dexamethasone Added to Bupivacaine on Postcesarean Pain Relief

Public title

Evaluating the Effect of Subcutaneous Dexamethasone Added to Bupivacaine on Postcesarean Pain Relief

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Parturients, ASA physical status I-II, scheduled for elective cesarean section, under general anesthesia. Exclusion Criteria: patients with suspected or manifest bleeding disturbances, allergy to Bupivacaine or Dexamethasone, atopia, diabetes mellitus, the presence of liver or kidney diseases, abuse of drugs and patients with pregnant induced hypertension or preeclampsia.

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 75

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

Isfahan University of Medical Sciences

Street address

Research Brueae, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2007-04-21, 1386/02/01

Ethics committee reference number

385552

Health conditions studied

1

Description of health condition studied

Complications of anaesthesia during pregnancy

ICD-10 code

O29.8

ICD-10 code description

Other complications of anaesthesia during pregnancy

Primary outcomes

1

Description

pain intensity

Timepoint

recovery room ,6 , 12, 24, 48 and 72 hours postoperative

Method of measurement

Visual Analogous Scale (VAS) and scoring from 0 to 10

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

at recovery room ,6 , 12, 24, 48 and 72 hours postoperative

Method of measurement

using mercury manometer

2

Description

Diastolic blood pressure

Timepoint

at recovery room ,6 , 12, 24, 48 and 72 hours postoperative

Method of measurement

using mercury manometer

3

Description

opioid consumption

Timepoint

at recovery room ,6 , 12, 24, 48 and 72 hours postoperative

Method of measurement

mili gram of opioid

4

Description

Heart rate

Timepoint

at recovery room ,6 , 12, 24, 48 and 72 hours postoperative

Method of measurement

Using EKG Monitoring

Intervention groups

1

Description

bupivacaine 20 ml,0.25% (SC) + dexamethasone 4 ml (16 mg) (SC) +Normal saline 4 ml iv, Duration of treatment: single dose .

Category

Treatment - Drugs

2

Description

bupivacaine 20 ml,0.25%(SC) + dexamethasone 4 ml (16 mg) iv+ Normal saline 4 ml iv, Duration of treatment: single dose .

Category

Treatment - Drugs

3

Description

bupivacaine 20 ml,0.25% (SC) + normal saline 4 ml SC+ normal saline 4 ml iv (placebo group). Duration of treatment: single dose .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra General Hospital

Full name of responsible person

Dr. Mitra Jabalameli

Street address

Department of Anesthesia and intensive care, Alzahra General Hospital, sofe Boulevard

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Ms. Leila Bakhshi

Street address

Research Brueae, Medical School, Isfahan University of Medical Sciences

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Isfahan

Grant name

385552

Grant code / Reference number

385552

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

Yes

Title of funding source

Isfahan 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

Research Brueae, Medical School, Isfahan University of Medical Sciences

Full name of responsible person

Ms. Leila Bakhshi

Position

Research BS

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Specialist and Associate professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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