Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Intrathecal Betamethasone on Post Operative Pain Relief after Cesarean Section in Mosavi Hospital.

Protocol summary

Summary

In this study, we evaluated the effect of intrathecal (IT) betamethasone as an adjunct to bupivacaine on postoperative pain in patients undergoing cesarean section. In a randomized, double-blind study, 99 patients undergoing cesarean section were randomly assigned to one of the following three groups. Group 1 (Control) received normal saline 0.5 ml IV with 3 ml of 0.5% heavy bupivacaine plus 0.5 ml of 0.9% saline intrathecally. Group 2 (IT) received normal saline 0.5 mL IV with 3 ml of 0.5% heavy bupivacaine plus 0.5 ml preservative free betamethasone (4 mg/ml) intrathecally. Group 3 (IV) received betamethasone 0.5 mL IV (4 mg/ml) with 3 ml of 0.5% heavy bupivacaine plus 0.5 ml of 0.9% saline intrathecally. After surgery, diclofenac 100 mg in suppository form was administrated as needed for analgesia. Postoperative diclofenac requirements, time to first analgesic administration and visual analogue scale (VAS) pain scores were recorded by a blinded observer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012115363N1**
Registration date: **2011-01-28, 1389/11/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-28, 1389/11/08

Registrant information

Name

Taraneh Naghibi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 2865

Email address

tnaghibi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Intrathecal Betamethasone on Post Operative Pain Relief after Cesarean Section in Mosavi Hospital.

Public title

The Effect of Intrathecal Betamethasone on Post Operative Pain Relief after Cesarean Section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I and II, age between 20 and 40 years old, scheduled to undergo Cesarean Section
Exclusion criteria: Receiving analgesics or corticosteroids drugs, presence of contraindication to regional anesthesia, known hypersensitivity to the study drugs or if having any history of cardiac, respiratory, neuromuscular, Hepatic or renal disease, unwilling to

participate

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **99**

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
Zanjan University of Medical Sciences

Street address
Azadi Blvd., Zanjan, Iran

City
Zanjan

Postal code

Approval date
2009-09-18, 1388/06/27

Ethics committee reference number
880627

Health conditions studied

1

Description of health condition studied
post operative pain

ICD-10 code
R52.0

ICD-10 code description
Acute pain

Primary outcomes

1

Description
severity of pain

Timepoint
4, 6, 12, 24 h after operation

Method of measurement
VAS-consisting of 100 mm line with 0 = no pain and 100 = worst possible pain

Secondary outcomes

1

Description
number of used suppository

Timepoint
24 hrs after surgery

Method of measurement
Asking from Patient

2

Description
Nausea and vomiting intraoperatively

Timepoint
At the end of the surgery

Method of measurement
Asking from Patient

3

Description
Nausea and vomiting postoperatively

Timepoint
24 hrs after surgery

Method of measurement
Asking from Patient

4

Description
headache after surgery

Timepoint
24 hrs after surgery

Method of measurement
Asking from Patient

5

Description
Time to rescue analgesic drug for the first time

Timepoint
Whenever the VAS goes higher than 4

Method of measurement
Asking from Patient

Intervention groups

1

Description
Group 2 (IT): Visual analogue scale for pain was explained to all patients during the preoperative visit. In the operating room routine monitors were established (electrocardiogram, non-invasive blood pressure monitor

and pulse oximeter). A 16 gauge intravenous canula was sited. An intravenous preload of 5 ml/kg of lactated Ringer's solution was given before dural puncture. Spinal puncture was performed at the L3-4 space with a 23-gauge Quincke needle by using a midline approach. The patients received normal saline 0.5 mL IV with 3 ml of 0.5% heavy bupivacaine plus 0.5 ml preservative free betamethasone (4 mg/ml) intrathecally. After surgery, diclofenac, 100 mg in suppository form was administrated as needed for analgesia.

Category

Treatment - Drugs

2

Description

Group 1 (Control): Visual analogue scale for pain was explained to all patients during the preoperative visit. In the operating room, routine monitors were established (electrocardiogram, non-invasive blood pressure monitor and pulse oximeter). A 16 gauge intravenous canula was sited. An intravenous preload of 5 ml/kg of lactated Ringer's solution was given before dural puncture. Spinal puncture was performed at the L3-4 space with a 23-gauge Quincke needle by using a midline approach. The patients received normal saline 0.5 mL IV with 3 ml of 0.5% heavy bupivacaine plus 0.5 ml of 0.9% saline intrathecally. After surgery, diclofenac, 100 mg in suppository form was administrated as needed for analgesia.

Category

Treatment - Drugs

3

Description

Group 3 (IV): Visual analogue scale for pain was explained to all patients during the preoperative visit. In the operating room routine monitors were established (electrocardiogram, non-invasive blood pressure monitor and pulse oximeter). A 16 gauge intravenous canula was sited. An intravenous preload of 5 ml/kg of lactated Ringer's solution was given before dural puncture. Spinal puncture was performed at the L3-4 space with a 23-gauge Quincke needle by using a midline approach. The patients received betamethasone 0.5 mL IV (4 mg/ml) with 3 ml of 0.5% heavy bupivacaine plus 0.5 ml of 0.9% saline intrathecally. After surgery, diclofenac, 100 mg in suppository form was administrated as needed for analgesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mosavi hospital

Full name of responsible person

Dr Taraneh Naghibi

Street address

Mosavi hospital, Gavazang Blvd, Zanjan, Iran

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor for Research of Zanjan University

Full name of responsible person

Alireza Biglari MD, PhD

Street address

Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi Blvd

City

Zanjan

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 of Zanjan University

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr Faramarz Dobakhti

Position

PhD, Assistant Professor

Other areas of specialty/work

Street address

Faculty of pharmacy, Zanjan University of Medical Sciences

City

Zanjan

Postal code

Phone

+98 24 1427 3636

Fax

Email

fdobakhti@zums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Taraneh Naghibi
Position
Anesthesiologist- Assistant Professor
Other areas of specialty/work
Street address
Mosavi hospital, Gavazang Blvd, Zanjan, Iran
City
Zanjan
Postal code
Phone
+98 24 1424 2712
Fax
Email
tnaghibi@zums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Faramarz Dobakhti
Position
PhD, Assistant Professor
Other areas of specialty/work
Street address
Faculty of pharmacy, Zanjan University of Medical Sciences
City
Zanjan
Postal code
Phone
Fax
Email
Web page address

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