Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A Clinical Trial to Assess the Effect of Combination of Interathecal Dexamethasone with Lidocaine and Narcotics on Post Cesarean Section Pain

Protocol summary

Summary

Objectives: To assess the effect of combination of the dexamethasone with local anesthetics and narcotics on enhancing the duration of painlessness and reducing the need for intravenous drugs for post cesarean pain control. Research Design: Conduction of a randomized, double-blind, clinical trial, method of randomization: simple randomization by computer . Inclusion criteria: women with a gestational age of 38-42 weeks; ASA I and II and literate. Exclusions criteria: pregnant woman who had received any analgesics during the prior 48 hours; addiction to the drugs ; hypersensitive to the administered drugs (lidocaine, dexamethasone, morphine); positive history of mental illness. Interventions: The parturients were divided into three equal groups to receive either 70 mg lidocaine intrathecally or 70 mg lidocaine combined with 0.15 mg morphine, or the latter regimen combined with 4 mg dexamethasone. For the first group, spinal anesthesia was done by using 70 mg lidocaine and no intravenous or intramuscular analgesics, or any other intrathecal drug. In the second group, we used 70 mg lidocaine in combination with 0.15 mg morphine 70 mg lidocaine, 0.15 mg morphine, and 4 mg dexamethasone were used for the third group,. Various variables such as pain intensity and amount of morphine administered as well as neonates' Apgar scores and duration of stay in the recovery room were compared between the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060819470N22**
Registration date: **2015-08-06, 1394/05/15**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-08-06, 1394/05/15

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2009-07-01, 1388/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial to Assess the Effect of Combination of Interathecal Dexamethasone with Lidocaine and Narcotics on Post Cesarean Section Pain

Public title

The Effect of l Dexamethasone on Post Cesarean Section

Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women with a gestational age of 38-42 weeks; ASA I and II; literate. Exclusions criteria: pregnant woman who had received any analgesics during the prior 48 hours; addiction to the drugs ; hypersensitivity to the administered drugs (lidocaine, dexamethasone, morphine); positive history of mental illness.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shiraz University Of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

CP-P-9334-1124

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

032.5

ICD-10 code description

Maternal care for multiple gestation with malpresentation of one fetus or more

Primary outcomes

1

Description

postoperative pain

Timepoint

At 4 ,8,12,24 hours after surgery

Method of measurement

NRS(Numerical Rating Scale)

Secondary outcomes

1

Description

Apgar

Timepoint

At the first and fifth min after birth

Method of measurement

Apgar Scoring

Intervention groups

1

Description

70 mg lidocaine intrathecally for spinal anesthesia

Category

Treatment - Drugs

2

Description

70 mg lidocaine combined with 0.15 mg morphine for spinal anesthesia

Category

Treatment - Drugs

3

Description

70 mg lidocaine with 4 mg dexamethasone for spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinabieh Teaching Hospital

Full name of responsible person

Behzad Maghsodi
Street address
Defae Moghadas square, Zeinabieh Teaching Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical S
Full name of responsible person
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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, Shiraz University of Medical S
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

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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