

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Effect of intravenous lidocaine on postoperative analgesia in cesarean section under spinal anesthesia

Protocol summary

Summary

Objective: Evaluating the analgesic efficacy of intravenous lidocaine in patients undergoing cesarean section under spinal anesthesia. Design: this study will be a randomized, double-blinded, placebo-controlled clinical trial in Kowsar teaching hospital in Qazvin. Setting and conduct: Following Ethics Committee approval and informed patients consent, eighty parturient patients ASA physical status I or II, scheduled for cesarean section under spinal anesthesia will be randomly allocated to one of two groups of 40 each. The lidocaine group (group L) will receive, 1.5 mg/kg of bolus Lidocaine 2% intravenously 15 minutes before spinal anesthesia and infusion of Lidocaine 2%(1.5 mg/kg/h) for one hour after beginning of surgery. The control group will receive bolus dose of Normal Saline intravenously instead of Lidocaine (in same volume of Lidocaine based on milliliter) 15 min before spinal and maintenance dose of Normal Saline will continue one hour from beginning of surgery. Time to first analgesic requirement after surgery, duration of sensory and motor blockade, hemodynamics variables and Adverse events such as hypoxia (oxygen (SpO₂)<90], bradycardia, hypotension, nausea and vomiting will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610023051N11**

Registration date: **2016-12-09, 1395/09/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Marzieh Khezri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous lidocaine on postoperative analgesia in cesarean section under spinal anesthesia

Public title

Evaluation of analgesic efficacy of lidocaine infusion in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Elective cesarean surgery; patients aged 18 to 45 years, ASA class 1 and 2. Exclusion criteria: complete heart block; Severe bleeding and

coagulation disorder; Severe hypotension and shock; septicemia; history of CNS disease; hyperthyroidism; hypertension; history of hepatorenal disease; Cardiovascular disease; diabetes; Allergy to lidocaine; placenta praevia; Placental abruption; cesarean induced deceleration Fetal heart rate (FHR); meconium; addict; contradiction of regional analgesia; eclampsia and preeclampsia; user of Beta blocker and glycoside.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random sampling is based on selection of colorful cards

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Qazvin University of Medical Sciences

Street address

Qazvin, Shahid Bahonar Blvd

City

Qazvin

Postal code

Approval date

2015-12-09, 1394/09/18

Ethics committee reference number

IR.QUMS.REC.1394.216

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Time to first analgesic requirement

Timepoint

During 24 hrs after the surgery

Method of measurement

Hour

2

Description

Sensory block level and recovery of sensory block to T10

Timepoint

30 and 60 seconds after injection

Method of measurement

Pin prick method

3

Description

Motor block level and recovery of motor block

Timepoint

30 and 60 seconds after injection

Method of measurement

Bromage scale

4

Description

Hemodynamic changes (bradycardia, hypotension and Oxygen saturation <90])

Timepoint

From the time of intervention; every 5 minute until 15 minute then every 15 minute until 1 hour

Method of measurement

Monitoring devise

Secondary outcomes

1

Description

Secondary effects

Timepoint

During 6 hrs after the surgery

Method of measurement

According patient's history

2

Description

Neonate APGAR

Timepoint

In the first and fifth minute from birth

Method of measurement

APGAR criteria

Intervention groups

1

Description

In control group, we injected bolus dose of Normal Saline intravenously instead of Lidocaine.(in same volume of Lidocaine based on milliliter) 15 min before spinal anesthesia. then maintenance dose of Normal saline continue one Hour from beginning of surgery

Category

Placebo

2

Description

In treatment group, 15 minutes before spinal anesthesia, 1.5 mg/kg of bolus Lidocaine 2% injected intravenously then, we infuse maintenance dose of IV Lidocaine 2%(1.5mg/kg/h) and Infusion of drug should be continue one Hour from beginning of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Koosar hospital

Full name of responsible person

Dr. Maryam Rajabi

Street address

Valiasr street, Qazvin.

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Blvd, Qazvin

City

Qazvin

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 Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Maryam Rajabi

Position

Assistant of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor of Anesthesiology

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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