Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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

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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
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Person responsible for scientific inquiries

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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