Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effects of intravenous lidocaine on postoperative pain in elective cesarean section with spinal anesthesia in fatemieh hospital of hamedan • spinal anesthesia in fatemieh hospital of hamedan in 1389.

Protocol summary

Summary

Parturient patients (72 patients) are admitted to fatemieh hospital of hamedan candidate for elective cesarean section in 1389, are described about procedure and after signation of consent forms,if they have not excluded criteria, divided to two groups of treatment and control in accidence (random block). The study is double blind and non of patients and nurses aware of administered drugs(The syringes of dugs are coded). In treatment group, 15 minutes before spinal anesthesia, 1.5 mg/kg of bolous lidocaine 2% is injected intravenously. Then patients are spinal anesthetized with 12.5 mg. marcaine 0.5% and 2.5 micrograms of sterile sufentanil with spinal needle No.25 .After prep and drape and in time of beginning of skin incision by surgeon, infusion of maintenance drug is initiated in treatment group,1.5mg./kg./h iv lidocaine 2%. Infusion of drug continue half past end of surgery in recovery unit. After then,drug is discontinued.In control group,we use normal salin intravenously instead of lidocaine.The volume of normal salin is the same of lidocaine, based on milliliter(15 min. before spinal anesthesia , bolous dose of normal salin is injected, Then patients are anesthetized spinaly with 12.5 mg. marcaine 0.5% and 2.5 micrograms of sterile sufentanil with spinal needle No.25 ,and just in time of skin incision, maintenance dose of normal salin is iniciated until half past end of surgey,in recovery unit). During study, the patients are monitored completely and vital signs are recorded. The severity of pain is recorded in 15 min. before spinal anesthesia, just before spinal anesthesia, 5 min. later, and then, 10 min., 15 min. ,30 min., 1hour, 2, 4, 6, 12, 24 hours after that by V.A.S.(visual analog scale) criteria. This criteria is used for assessment of severity of pain and has 0 to 10 scores. The patient asked for this score . all scores recorded. 0 score means completely without pain and 10 score means terrible pain. An upper score reveals more pain. if the patient suffer from pain during this study, with scores above 4,analgesic drugs are used. If the score. is 4-6 , supp. Diclofenac Na. 100mg. are administered and if the score is 7-10 , intravenous morphin sulfate are used. The name and rate of analgesic drugs are recorded. The main goal of this study is whether iv lidocaine in contrast with placebo could has analgesic effects on spinal anesthetized cesarean section patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012113954N5**
Registration date: **2011-03-01, 1389/12/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-01, 1389/12/10

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research and technology, Hamedan

University Of Medical Science

Expected recruitment start date
2010-11-07, 1389/08/16
Expected recruitment end date
2011-02-19, 1389/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of intravenous lidocaine on postoperative pain in elective cesarean section with spinal anesthesia in fatemieh hospital of hamedan • spinal anesthesia in fatemieh hospital of hamedan in 1389.

Public title
The effects of intravenous lidocaine on postoperative pain in cesarean section with spinal anesthesia anesthesia.
Purpose
Other
Inclusion/Exclusion criteria
Excluding criteria:1-urgent or emergent cesarean section. 2-pregnancy by ivf. 3-history of low back pain. 4-preterm labor. 5-arrythmia before and during surgery. 6-liver,cardiac or renal failure of parturient. 7-refuse of consent. 8-usage of analgesic drugs during past 3 days. INCLUDING criteria: Elective cesarean in term parturients.
Age
From **15 years** old to **47 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **72**
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
Ethics Committee Of Hamedan University Of Medical Scince
Street address
Vince Chancelor For Research And Technology, Hamedan University Of Medical Science
City
Hamedan
Postal code

Approval date
2011-02-14, 1389/11/25
Ethics committee reference number
p/16/35/9/176708

Health conditions studied

1

Description of health condition studied
pain relief
ICD-10 code
094-099
ICD-10 code description
Other Obstetric Conditions, That Are Not Classified Elsewhere

Primary outcomes

1

Description
Pain
Timepoint
15min before spinal anesthesia, just before spinal anesthesia, 5 min., 10 min., 15 min., 30 min., 1 hour, 2 hour, 4 hour, 6 hour, 12 hour, 24 hour after beginnig infusion of drugs.
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Arrythmia
Timepoint
Continuous Monitoring
Method of measurement
Continuous EKG Monitoring

Intervention groups

1

Description
In intervention group, 1.5 mg/kg of intravenous lidocaine are injected bolous, 15 minutes before initiation of

incision, and 1.5mg/kg/min of intravenous lidocaine are infused until half past enterance the patient to recovery unit

Category

Treatment - Drugs

2

Description

in contrl group normal sailine was intravenously infused in volume the same as lidocaein

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Fatemieh Hospital

Full name of responsible person

Armin Amini

Street address

Fatemieh Hospital, Pasdaran Street, Hamedan, Iran

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research And Technology

Full name of responsible person

Dr. Mohammad Hossein Bakhshaei

Street address

Vice Chancellor For Research, Hamedan University Of Medical Science

City

Hamedan

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 And Technology

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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Armin Amini

Position

Resident of anesthesia

Other areas of specialty/work

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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