Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Randomized trial to determination of minimal dose of Lidocaine with Sufentanil‘s fixed dose in spinal anesthesia for cesarean section.

Protocol summary

Summary

(1) Introduction and background: Cesarean is one of the most common gynecologic operations and spinal anesthesia is considered as one of the usual anesthesia methods in such operations. Lidocaine might lead to complications such as nausea, vomiting, hypotension, bradycardia and etc... Using an appropriate combination of Lidocaine and Sufentanil might be very significant for its possible effect in reducing these complications and Inducing an appropriate post-operative analgesia and desired spinal level. Considering the great number of such patients, studying this combination is very significant. (2) Objectives: In the present research, attempt will be made to achieve the appropriate minimal dose of Licocaine which will likely bring about the optimum analgesia level and minimal side effects for the patients. (3) Design: Randomized Controlled Trial (4) Setting and conduct: Study conduct on patients admitted for Cesarean section in Imam Reza (AS) Hospital in Kermanshah City, Iran. (5) Participants including major eligibility criteria: The subjects were seventy patients in ASA class I & II, candidate for Cesarean. Following their informed consent, they were randomly assigned into three groups. In all patients fixed doses of Sufentanil and Epinephrine and different doses of Lidocaine were used. Spinal anesthesia was then induced in sitting position using whitecare needle at lumbar four– lumbar five interspaces. (6) Intervention: The intervention A group will be received Intrathecal injection of seventy five milligram lidocaine plus two point five micro gram sufentanil (forty two patients). The intervention B group will be received Intrathecal injection of sixty milligram lidocaine plus two point five µg sufentanil (forty two patients). The intervention C group will be received Intrathecal injection of fifty milligram lidocaine plus two point five micro gram sufentanil (forty two patients). (7) Main outcome measures (variables): The Severity of pain, nausea and vomiting in post operative period will be measured by Visual analogue Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102071310N7**
Registration date: **2011-02-24, 1389/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-02-24, 1389/12/05

Registrant information

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Alireza Ahmadi
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Science,

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Randomized trial to determination of minimal dose of Lidocaine with Sufentanil‘s fixed dose in spinal anesthesia for cesarean section.

Public title
Determination of minimal dose of Lidocaine with Sufentanil‘s fixed dose in spinal anesthesia for cesarean section.

Purpose
Treatment

Inclusion/Exclusion criteria
Exclusion criteria: All patients who are not class I and II ASA; Patients not signed the informed consent; Patients with underlying disease; Patients with chronic pain or; Who have used analgesic medications in the past forty eight hours; Patients with abscess or local infection at the injection site; Severe agitation; Cerebral disorder; Severe psychological disorders and addiction;

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **126**

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
Ethics committee of Kermanshah University of Medical Science

Street address
Shahid Beheshti Boulevard, Kermanshah,

City
Kermanshah

Postal code
67188

Approval date
2009-11-24, 1388/09/03

Ethics committee reference number
674

Health conditions studied

1

Description of health condition studied
Delivery by elective caesarean section

ICD-10 code
O82.0

ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Severity of pain

Timepoint
every three minute after procedure.

Method of measurement
Visual analogue Scale.

2

Description
Nausea and Vomiting

Timepoint
Two and twenty four hours postoperative

Method of measurement
have, or not have

Secondary outcomes

1

Description
Blood Pressure

Timepoint
Once before spinal then every three minute after procedure with Datascope, Model: Pse-420

Method of measurement
mm Hg

2

Description
Heart Rate

Timepoint
Once before spinal then every three minute after procedure with Datascope model: Pse-420

Method of measurement
Number per minute

Intervention groups

1

Description
Intrathecal injection of 75mg lidocaine+ 2.5 µg sufentanil

in group A(42 patients).

Category

Treatment - Drugs

2

Description

Intrathecal injection of 60mg lidocaine+2.5 µg sufentanil in group B(42 patients).

Category

Treatment - Drugs

3

Description

Intrathecal injection of 50mg lidocaine+2.5µg sufentanil in group C(42 patients).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Parisa Golfam

Street address

Parastar Boulvard, Imam Reza Hospital, Kermanshah, Iran

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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67188, Shahid Beheshti Boulevard, Kermanshah University of Medical Sciences, Research Department

City

Kermanshah

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 Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Parisa Golfam

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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