

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of intravenous Lidocaine on pain intensity after Cesarean section

Protocol summary

Summary

This study is a double-blind randomized clinical trial (RCT). The aim of this study is to evaluate the Effect of intravenous Lidocaine on pain intensity after Cesarean section. 100 patients, who qualified for study entry, randomly allocate in two equal intervention and control groups. Inclusion criteria are: willingness to enter the study and informed written consent; ASA class 1&2; Elective cesarean surgery; Age between 20 and 35 years. Exclusion criteria are: Unwillingness to continue the study; Known lidocaine sensitivity; surgery time more than 1/5 hours; Midline incision for any reason; Any unusual complication during surgery. Intervention group receive Lidocaine IV 1/5 mg/Kg and control group receive Normal saline during induction of anesthesia. During 24 hours after surgery pain intensity (VAS), prescribed diclofenac suppository (100 mg if VAS>3) and IV morphine (3 mg if VAS>5), Nausea and vomiting, Patient satisfaction of pain control are measured in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408114365N17**
Registration date: **2014-08-20, 1393/05/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-20, 1393/05/29

Registrant information

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous Lidocaine on pain intensity after Cesarean section

Public title

Effect of intravenous Lidocaine on pain intensity after Cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness to enter the study and informed written consent; ASA class 1&2; Elective cesarean surgery; Age between 20 and 35 years. Exclusion criteria: Unwillingness to continue the study; Known lidocaine sensitivity; surgery time more than 1/5 hours; Midline incision for any reason; Any unusual complication during surgery.

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: **100****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**

Ethic committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

46175866

Approval date

2013-02-02, 1391/11/14

Ethics committee reference number

91-212

Health conditions studied**1****Description of health condition studied**

pain intensity after Cesarean section

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes**1****Description**

Pain intensity

Timepoint

2, 4, 6, 12, 24 hour after surgery

Method of measurement

VAS) Visual Analog Scale

Secondary outcomes**1****Description**

Patient satisfaction of pain control

Timepoint

During 24 hours after surgery

Method of measurement

Data collecting form

2**Description**

Nausea and vomiting

Timepoint

During 24 hours after surgery

Method of measurement

Data collecting form

3**Description**

Used morphine amount

Timepoint

During 24 hours after surgery

Method of measurement

Data collecting form

4**Description**

Used diclofenac amount

Timepoint

During 24 hours after surgery

Method of measurement

Data collecting form

Intervention groups**1****Description**

Intervention group: Lidocaine IV 1/5 mg/Kg is infused during induction of anesthesia.

Category

Treatment - Drugs

2**Description**

Control group: Normal saline is infused during induction of anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini General Hospital

Full name of responsible person

afshin gholipour baradari, MD, CCMF, associate professor

Street address

Imam Khomeini general Hospital, Amir St.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati, MD

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Mazandaran university of medical sciences, Moallem Square- Sari- Iran

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Sari

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 Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Afshin Gholipour Baradari, MD

Position

CCMF, Associate Professor, Chief of ICU

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