

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of intraperitoneal instillation of Lidocaine on the postoperative pain after cesarean delivery

Protocol summary

Study aim

The effect of intraperitoneal instillation of Lidocaine on the postoperative pain after cesarean delivery

Design

Randomized clinical trial with parallel intervention and control group, in which 200 patients are randomly assigned to two groups of intervention and control.

Settings and conduct

This study is conducted at Ommol-Banin Hospital and on the pregnant women who are candidates for cesarean section surgery. They are randomly assigned to either the intraperitoneal instillation of Lidocaine or normal saline groups. The patient, surgeon and caregiver are unaware of the type of medication used for the mother.

Participants/Inclusion and exclusion criteria

Inclusion: All pregnant women with singleton pregnancy / candidate for elective cesarean section with spinal anesthesia / between 18 to 45 years / body mass index (BMI) less than 40 / one previous cesarean section with pfannenstiell incision. Exclusion: history of other abdominal surgery / history of chronic pain / history of cardiac arrhythmia / Sensitivity to the drugs which are used in the intervention group.

Intervention groups

After delivery of the neonate and placenta, and the surgeon satisfaction with hemostasis, a sterile 20-mL syringe containing 2% lidocaine with epinephrine 1:200,000 is given to the surgeon. Then she carefully instills the study drug on the uterine peritoneal area by spraying two third of the drug around the uterine spaces and one third in the incision location. In the placebo group, this syringe will contain normal saline only.

Main outcome variables

The post - operative level of pain is measured at 6, 12, and 24 hours after the surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190227042862N1**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **retrospective**

Last update: **2019-05-23, 1398/03/02**

Update count: **0**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

Razieh Hadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 7762

Email address

hadir931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intraperitoneal instillation of Lidocaine on the postoperative pain after cesarean delivery

Public title

The effect of intraperitoneal instillation of Lidocaine on the postoperative pain after cesarean delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All pregnant women with singleton pregnancy between 18 to 45 years body mass index (BMI) less than 40 one previous cesarean section with pfannenstiell incision candidate for elective cesarean section with spinal anesthesia

Exclusion criteria:

history of other abdominal surgery history of chronic pain history of cardiac arrhythmia Sensitivity to the drugs which are used in the intervention group

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant women will be randomly assigned to one of the intervention or control groups by choosing one of the sealed envelopes (including the group name).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of receiving medication or placebo. Syringes containing the medication or placebo have the same appearance and are given to the surgeon as coded syringes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-11-26, 1397/09/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.429

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.0

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Post-operative pain

Timepoint

6, 12 and 24 hours after cesarean section.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After delivery of the neonate and placenta, and the surgeon satisfaction with hemostasis, a sterile 20-mL syringe containing 2% lidocaine with epinephrine 1:200,000 is given to the surgeon. Then she carefully instills the study drug on the uterine peritoneal area by spraying two third of the drug around the uterine spaces and one third in the incision location.

Category

Treatment - Drugs

2

Description

Control group: After delivery of the neonate and placenta, and the surgeon satisfaction with hemostasis, a sterile 20-mL syringe containing normal saline is given to the surgeon. Then she carefully instills the study drug on the uterine peritoneal area by spraying two third of the drug around the uterine spaces and one third in the incision location.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin hospital

Full name of responsible person

Razieh Hadi

Street address

16th Bahjat street, Ayatollah Bahjat avenue,
Mashhad, Iran

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Email

hadir931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah Ave.

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Razieh Hadi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Razieh Hadi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The final article

When the data will become available and for how long

One year after publication.

To whom data/document is available

for people working in academic institutions.

Under which criteria data/document could be used

To conduct meta-analysis studies.

From where data/document is obtainable

Via Email

What processes are involved for a request to access data/document

After email reception.

Comments