Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 pfannenstiel 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 pfannenstiel 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9144734767
Phone
+98 51 3223 5601
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.
City
Mashhad
Province
Razavi Khorasan
Postal code
917751365
Phone
+98 51 3278 2261
Email
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
Street address
16th ayatollah Bahjat ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9144734767
Phone
+98 51 3278 2261
Email
hadir931@mums.ac.ir

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
Street address
16th ayatollah Bahjat ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9144734767
Phone
+98 51 3278 2261
Email
hadir931@mums.ac.ir

Person responsible for updating data

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
Street address
16th ayatollah Bahjat ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9144734767
Phone
+98 51 3278 2261
Email
hadir931@mums.ac.ir

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