Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparative study of the duration of analgesia following spinal anesthesia with lidocaine 5% with fentanyl and marcain in pregnant women under cesarean section

Protocol summary

Summary

Objective: To compare the duration of analgesia after spinal anesthesia with lidocaine 5% with fentanyl and Marcaine in pregnant women undergoing caesarean section study design: non-randomized, double-blind (Patient and investigator), without control mode, single-center, Phase 2 clinical trial Study population: Non-emergency pregnant patients refer to caesarean section. Major inclusion criteria: Non-emergency pregnancy patients referred for cesarean section. Main Exclusion criteria: People with a history of diabetes, addiction, sedation And psychotropic drugs. Sample size: 200 patients Intervention: Effect of marcaine and lidocaine 5% with fentanyl on the duration of return of pain level in pregnant mothers under spinal anesthesia. Intervention time: initiation of cesarean section. Outcome: Effect of Lidocaine 5% with fentanyl and marcaine is different in duration of analgesia following spinal anesthesia in pregnant women under cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707157745N9**
Registration date: **2017-08-12, 1396/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-12, 1396/05/21

Registrant information

Name

Afshin Mansourian

Name of organization / entity

YUMS

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-09-11, 1396/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the duration of analgesia following spinal anesthesia with lidocaine 5% with fentanyl and marcain in pregnant women under cesarean section

Public title

Clinical trial comparing lidocaine 5% with fentanyl and Marcaine on the duration of spinal anesthesia in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant patients who come to the operating room for non-emergency c/s. Exclusion criteria: patients with a history of diabetes, addiction, drugs are sedatives and psychoactive drugs.

Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
In this study, the satisfaction of mothers with surgery was studied in both groups.

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Deputy of Research and Technology of YUMS
Street address
Yasuj University of Medical Sciences
City
Yasuj
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
IR.YUNS.REC.1395.221

Health conditions studied

1

Description of health condition studied
Spinal Anesthesia in pregnant patient
ICD-10 code
XV
ICD-10 code description
094-099

2

Description of health condition studied
Spinal Anesthesia in pregnant patient
ICD-10 code
XV
ICD-10 code description
094-099

Primary outcomes

1

Description
the duration of analgesia after spinal anesthesia with lidocaine 5% with fentanyl and Marcaine in pregnant women undergoing cesarean section.
Timepoint
5 minutes after completion of caesarean section, Back pain at the site of action
Method of measurement
Touch the place

Secondary outcomes

1

Description
Satisfaction and a pleasant feeling by the mother
Timepoint
After the surgery and recovery time
Method of measurement
Ask the patient and see the clinical symptoms

Intervention groups

1

Description
Marcaine injected in the subarachnoid space in a single dose, 4 mg
Category
Treatment - Drugs

2

Description
We use two drugs in this study. Lidocaine 5%: injection in the subarachnoid space as a single dose of 75 mg Fentanyl: injection in the subarachnoid space as a single dose ,50 macro grams Marcaine: injected in the subarachnoid space as a single dose, 4 mg
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hospital
Full name of responsible person
Dr. Afshin Mansourian
Street address
Shahid Behashti haspital
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, YUMS
Full name of responsible person
Dr Hossein Ariad
Street address
YUMS
City
Yasuj
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, YUMS
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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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*