

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 marcaïn 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 caesarean section. Main Exclusion criteria: People with a history of diabetes, addiction, sedation And psychotropic drugs. Sample size: 200 patients Intervention: Effect of marcaïn 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 marcaïn 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)

Phone

+98 74 3322 0620

Email address

afshin.mansourian@yahoo.com

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 marcaïn 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 hospital

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

YUMS

Full name of responsible person

DR.Afshin Mansourian

Position

Anesthesiologist / Assistant Professor

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

