

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effect of addition of Dexmedetomidine and Fentanyl to Lidocaine 5% in spinal anesthesia to increase postoperative analgesia in women candidate elective cesarean

Protocol summary

Summary

Aim of this study is comparison effect of addition of Dexmedetomidine and Fentanyl to Lidocaine 5% in spinal anesthesia to increase postoperative analgesia in women candidate elective cesarean. This study is clinical trial and double blind. 84 patient candidate elective cesarean in Taleghani hospital in Arak arrive this study. Inclusion criteria: 18 to 35 years; single pregnancy; candidate cesarean with spinal anesthesia; elective cesarean. Exclusion criteria: multiple pregnancy; allergy for Fentanyl and dexmedetomidine; infection in site of spinal anesthesia. We will divide patients in two groups randomly. We will inject 25 micro gram Fentanyl into Lidocaine 5% in first group and we will inject 30-35 micro gram (0/5 micro gram in kilogram) Dexmedetomidine into Lidocaine 5% in second group. We will record oxygen saturation, heart rate and blood pressure and breathing every 15 minute to end of surgery. We will record pain in recovery, 4 and 12 and 24 hours after cesarean by Visual Analog Scale. We will record duration of analgesia after cesarean by requesting the first analgesic drug after surgery and mean of analgesic drug use in 24 hours after cesarean.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012320258N28**
Registration date: **2017-01-31, 1395/11/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-31, 1395/11/12

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor research, Arak University of Medical Sciences

Expected recruitment start date

2016-08-21, 1395/05/31

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of addition of Dexmedetomidine and Fentanyl to Lidocaine 5% in spinal anesthesia to increase postoperative analgesia in women candidate elective cesarean

Public title

Comparison effect of addition of Dexmedetomidine and Fentanyl to Lidocaine 5% in spinal anesthesia in women candidate elective cesarean

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 18 to 35 years; single pregnancy; candidate cesarean with spinal anesthesia; elective cesarean. Exclusion criteria: multiple pregnancy; allergy for Fentanyl and dexmedetomidine; infection in site of spinal anesthesia; lack of consent.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features
Randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Arak University Of Medical Sciences
Street address
Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij square, Sardasht, Arak
City
Arak
Postal code
38149578558
Approval date
2016-08-08, 1395/05/18
Ethics committee reference number
IR.ARAKMU.MU.REC.1395.138

Health conditions studied

1

Description of health condition studied
Elective cesarean
ICD-10 code
O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description
Blood pressure
Timepoint
Every 5 minute to recovery
Method of measurement
millimeter Hg

2

Description
Heart rate
Timepoint
every 5 minute to recovery
Method of measurement
Beat in minute

3

Description
Oxygen saturation
Timepoint
every 15 minute to recovery
Method of measurement
Percent

4

Description
Breathing
Timepoint
Every 15 minute to recovery
Method of measurement
Number in minute

5

Description
Pain
Timepoint
In recovery and 4 and 12 and 24 hours after cesarean
Method of measurement
Visual Analogue Scale

6

Description
Duration of analgesia
Timepoint
requesting the first analgesic drug
Method of measurement
Miligram

7

Description
Narcotic drug

Timepoint

24 hours after cesarean

Method of measurement

Miligeram

Secondary outcomes

empty

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

Intervention group : We will inject 25 micro gram Fentanyl into Lidocaine 5%.

Category

Treatment - Drugs

2**Description**

Intervention group: we will inject 30-35 micro gram (0/5 micro gram in kilogram) Dexmedetomidine into Lidocaine 5%.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Hospital

Full name of responsible person

Dr Maryam Shokrpour

Street address

Taleghani Hospital, Emam Khomeini Street

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research, Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

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, Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Faculty, Anesthesiologist

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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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