Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compared the effects of adding Dexmedetomidine and tramadol to lidocaine 5% in the duration of postoperative analgesia in spinal anesthesia in women undergoing cesarean section

Protocol summary

Summary

Aim of this study compared the effects of adding Dexmedetomidine and tramadol to lidocaine 5% in the duration of postoperative analgesia in spinal anesthesia in women undergoing cesarean section. This study is clinical trials and double blind. 180 women will enter in this study. We will divide women in three groups (Dexmedetomidine and tramadol and placebo) randomly. We will check pain and duration analgesia and mean narcotic in 24 hours after cesarean and nausea and vomiting after 24 hours. Inclusion criteria: 20-40 years; cesarean elective candidate Taleghani hosbital; ASA I and II; lack of allergy in Lidocaine and Tramadol and Dexmedetomidine Exclusion criteria: failure in Spinal anesthesia; more than two attempts for spinal anesthesia; prolongation of surgery more than 90 minutes; Patients with substance abuse; patients with cardiovascular and pulmonary

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060620258N49**
Registration date: **2017-06-18, 1396/03/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-18, 1396/03/28

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Arak University of Medical Sciences

Expected recruitment start date

2016-04-29, 1395/02/10

Expected recruitment end date

2018-04-30, 1397/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compared the effects of adding Dexmedetomidine and tramadol to lidocaine 5% in the duration of postoperative analgesia in spinal anesthesia in women undergoing cesarean section

Public title

Compared the effects of adding Dexmedetomidine and tramadol to lidocaine 5% in the duration of postoperative analgesia in spinal anesthesia in women undergoing cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-40 years; cesarean elective candidate Taleghani hosbital; ASA I and II; lack of allergy

in Lidocaine and Tramadol and Dexmedetomidine
Exclusion criteria: failure in Spinal anesthesia; more than two attempts for spinal anesthesia; prolongation of surgery more than 90 minutes; Patients with substance abuse; patients with cardiovascular and pulmonary

Age
From **20 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
City
Arak
Postal code
38149578558
Approval date
2016-04-25, 1395/02/06
Ethics committee reference number
IR.ARAKMU.REC.1395.17

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
duration analgesia
Timepoint
24 hours after cesarean
Method of measurement
minute

2

Description
mean narcotic
Timepoint
24 hours after cesarean
Method of measurement
miligeram

3

Description
Pain
Timepoint
recavery and 4 and 12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale Questionnaire

4

Description
Nausa and vomitting
Timepoint
24 hours after cesarean
Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
Control group: We will inject 0.5 milliliter normal saline.
Category
Treatment - Drugs

2

Description
Intervention group: We will inject 25 milligram Teramadol (0.5 milliliter).
Category
Treatment - Drugs

3

Description
Intervention group: We will inject 25 milligram

Dexmedetomidine (0.5 milliliter).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr Alireza Kamali

Street address

Emam Khomeini street, Taleghani hospital

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 Anoshirvani

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 Maryam Shokrpour

Position

Faculty Member, Gynechologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Faculty Member, Anesthesiologist

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Person responsible for updating data

Contact

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Position

Medical Student

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
Data Dictionary
empty