

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

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 square, 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

miligram

3

Description

Pain

Timepoint

recovery and 4 and 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale Questionnaire

4

Description

Nausea and vomiting

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

Street address

Emam Khomeini street, Taleghani hospital

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 863222003

Email

alikalaliir@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Faculty Member, Anesthesiologist

Other areas of specialty/work

Street address

Shahid Shirodi street, Valiasr squire, Valiasr hospital

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 863222003

Email

alikalali@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Radmehr Aminloo

Position

Medical Student

Other areas of specialty/work

Street address

Complex Payambar azam, Basij squire, Sardasht, Arak

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 863222003

Email

alikalaliir@yahoo.com

Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>