

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of addition of neostigmine or tramadol to 1/5 percent lidocaine with paracervical block in reduce of post operative pain in colporrhaphy

Protocol summary

Summary

The aim of this study is effect of adding Neostigmine or Tramadol to Lidocaine 1.5 percent in reducing postoperative pain in patients with colporrhaphy under paracervical block in Taleghani Hospital in Arak. Inclusion criteria: age 30-55 years; ASA class 1 and 2. Exclusion criteria: ASA class 3 and 4; failure in paracervical block; duration surgical more than 90 minutes; body mass index more than 35. 108 patients divided randomize in the three groups. First group inject Neostigmine 50 microgram (equivalent to 0.5 milliliter) in Lidocaine 1.5 percent, in the second group inject Tramadol 25 milligram (equivalent 0.5 milliliter) in Lidocaine 1.5 percent and in the third group inject 0.5 milliliter Normal Saline in Lidocaine 1.5 percent. Researcher record oxygen saturation, ECG, respiration rate, temperature, blood pressure every 15 minutes during surgery and end of surgery and in recovery. Pain scale record at 2, 6, 12 and 24 hours after surgery. Researcher record average duration of analgesia for patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050320258N7**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

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Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Science

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of addition of neostigmine or tramadol to 1/5 percent lidocaine with paracervical block in reduce of post operative pain in colporrhaphy

Public title

Comparison of addition of neostigmine or tramadol to 1/5 percent lidocaine with paracervical block in reduce of post operative pain in colporrhaphy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 30-55 years; ASA class 1 and 2
Exclusion criteria: ASA class 3 and 4; failure in paracervical block; duration surgical more than 90

minutes; body mass index more than 35

Age

From **30 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Postal code

848176941

Approval date

2016-02-22, 1394/12/03

Ethics committee reference number

IR.ARAKMU.REC.1394.298

Health conditions studied

1

Description of health condition studied

Colporrhaphy

ICD-10 code

N81

ICD-10 code description

Female genital prolapse

Primary outcomes

1

Description

temprature

Timepoint

in, end of surgery to 24 hours

Method of measurement

Thermometer

2

Description

oxygen saturation

Timepoint

in, end of surgery to 24 hours

Method of measurement

oxymeter

3

Description

blood pressure

Timepoint

in, end of surgery to 24 hours

Method of measurement

barometer

4

Description

pain

Timepoint

in, end of surgery to 24 hours

Method of measurement

visual Analogue Scale

5

Description

duration of analgesia

Timepoint

after surgery

Method of measurement

minute

Secondary outcomes

empty

Intervention groups

1

Description

First group inject Neostigmine 50 microgram (equivalent to 0.5 milliliter) in Lidocaine 1/5 percent.

Category

Treatment - Drugs

2

Description

Second group inject Tramadol 25 miligeram (equivalent 0.5 cc) in Lidocaine 1/5 percent.

Category

Treatment - Drugs

3**Description**

Control group inject 0/5 milliliter Normal Saline in Lidocaine 1/5 percent.

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

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

Atefeh Khalilpour

Position

student of general medicine

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

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

Medicine department

Full name of responsible person

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Position

Anesthesiologist

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Arak University Of Medical Sciences

Full name of responsible person

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Position

student of medicine

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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