

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison addition morphine and Tramadol to 1.5% lidocaine with para cervical block in reducing of post operative pain in patient candidate curettage

Protocol summary

Summary

The objective of this study was to compare the level of sedation and postoperative pain in patients submitted to curettage. This study is double blind clinical trial. We enroll 120 women candidate for curettage. We divide patients to three equal groups. We inject 5 milliliter Lidocaine 1.5% plus 1 milliliter morphine (total 6 milliliter) in first group and we inject 5 milliliter Lidocaine 1.5% plus 2 milligram Tramadol (equal 1 milliliter) in second group and we inject 5 milliliter Lidocaine 1.5% plus 1 milliliter normal saline in third group. We record blood pressure, heart rate, O2 saturation in questionnaire every 5 minute during surgery. We evaluate postoperative pain in recovery, 30 and 60 minutes after operation by visual analogue scale. We record time of analgesic request in 24 hours. Inclusion criteria: age 20-45; ASA class I and II; block by one person; curettage by one person; duration of curettage in 20 minute. Exclusion criteria: failure in general anesthesia; history of underlying disease; allergy to drug of anesthesia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110720258N17**
Registration date: **2017-03-03, 1395/12/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-03, 1395/12/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice President of Research , Arak University of Medical Sciences

Expected recruitment start date

2015-10-12, 1394/07/20

Expected recruitment end date

2018-09-29, 1397/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison addition morphine and Tramadol to 1.5% lidocaine with para cervical block in reducing of post operative pain in patient candidate curettage

Public title

Comparison addition morphine and Tramadol to 1.5% lidocaine with para cervical block in reducing of post operative pain in patient candidate curettage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 45; ASA class I and II; block

by one person; curettage by one person; duration of curettage in 20 minute. Exclusion criteria: failure in general anesthesia; history of underlying disease; allergy to drug of anesthesia

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomize with random numbers table

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 squire, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2015-09-29, 1394/07/07

Ethics committee reference number

IR.ARAKMU.REC.1394.167

Health conditions studied

1

Description of health condition studied

Curettage surgery

ICD-10 code

o.04

ICD-10 code description

Medical abortion

Primary outcomes

1

Description

pain

Timepoint

in recovery , 30 and 60 minute after surgery

Method of measurement

visual Analogue Scale

2

Description

narcotic drug

Timepoint

after surgery

Method of measurement

miligeram

3

Description

blood pressure

Timepoint

every 5 minute until recovery

Method of measurement

millimeter Hg

4

Description

heart rate

Timepoint

every 5 minute to recovery

Method of measurement

count

5

Description

oxygen saturation

Timepoint

every 5 minute to recovery

Method of measurement

percent

Secondary outcomes

empty

Intervention groups

1

Description

We injected millimeter lidocaine 1.5% plus 1 millimeter morphine (total 6 millimeter) in first group.

Category

Treatment - Drugs

2

Description

We injected 5 millimeter lidocaine 1.5% plus 2 milligram Tramadol (equal 1 millimeter) in second group.

Category

Treatment - Drugs

3

Description

We injected 5 millimeter lidocaine 1.5% plus 1 millimeter normal saline administrated for paracervical block in third group.

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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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

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Position

resident of gynecology

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