

# 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

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 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

**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 Raheleh Rezaee Ashtiani

**Position**

resident of gynecology

**Other areas of specialty/work**

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**Position**

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**Web page address**

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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*