

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comprasion of adition of Dexmedetomidine and fentanyl to Lidocain 2% to reduce intra and post opraion pain in curettage procedered

Protocol summary

Study aim

Comparison of addition of Dexmedetomidine and fentanyl to Lidocain 2% to para cervical block reduce pain in patients candidates curettage proceeded

Design

The study will be double blind and clinical trial. 132 patients will be randomly divided into 2 groups. The groups will be parallel. The trial phase will be 3.

Settings and conduct

Candidate for curettage in Taleghani Hospital in Arak will be divided into 2 groups by simple randomization with envelopes. The study will be double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 40 years old, candidate for curettage up to 14 weeks of pregnancy
Exclusion criteria: Dissatisfaction

Intervention groups

Group 1: Lidocaine solution of 1.5% (5 cc) with dexmedetomidine and 10 micro grams equivalent to 1 millilitre (total 6 millilitre) will be used for paracervical block
Group 2: Lidocaine solution of 1.5% (5 cc) with Fentanyl in the amount of 50 micro grams equivalent to 1 millilitre (6 millilitre in total) will be used for paracervical block

Main outcome variables

Pain, nausea and vomiting, the amount of drugs consumed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N162**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comprasion of adition of Dexmedetomidine and fentanyl to Lidocain 2% to reduce intra and post opraion pain in curettage procedered

Public title

Compression of addition of Dexmedetomidine and fentanyl to Lidocain management pain in curettage proceeded

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18 to 40 years old Candidate for curettage up to 14 weeks of pregnancy

Exclusion criteria:
Dissatisfaction

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with random allocation with envelopes in 2 groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province
Markazi

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3848176941

Approval date
2021-01-31, 1399/11/12

Ethics committee reference number
IR.ARAKMU.REC.1399.319

Health conditions studied

1

Description of health condition studied

curettage

ICD-10 code

O00-O08

ICD-10 code description

Pregnancy with abortive outcome

Primary outcomes

1

Description

Pain

Timepoint

Up to 2 hours after surgery

Method of measurement

Visual analog pain questionnaire

2

Description

Nausea and vomiting

Timepoint

After surgery

Method of measurement

Observation

3

Description

Mean of drugs consumed

Timepoint

After surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lidocaine solution of 1.5% (5 cc) with dexmedetomidine and 10 micro grams equivalent to 1 milliliter (total 6 milliliter) will be used for paracervical block

Category

Treatment - Drugs

2**Description**

Intervention group: Lidocaine solution of 1.5% (5 cc) with Fentanyl in the amount of 50 micro grams equivalent to 1 milliliter (6 milliliter in total) will be used for paracervical block

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani hospital

Full name of responsible person

Dr Maryam Shokrpour

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Mshokrpour@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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Specialist

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Dr Mehrnosh Manzari

Position

Resident of gynecologist

Latest degree

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Other areas of specialty/work

Gynecology and Obstetrics

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Province

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available