

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison effect of topical Dexmedetomidine infiltration with subcutaneous Ketamine on postoperative pain in patients candidating abdominal hysterectomy under general anesthesia

Protocol summary

Summary

Aim of this study is comparison effect of topical Dexmedetomidine infiltration subcutaneous Ketamine on postoperative pain in patient's candidate abdominal hysterectomy under general anesthesia. This study is clinical trial. We divide 126 patients in 3 groups randomly (each group 42 person). Inclusion criteria: abdominal hysterectomy; general anesthesia; 30-65 years; duration of surgery maximum 120 minute; ASA I and II. Exclusion criteria: allergy for Dexmedetomidine and Ketamine; duration of surgery more than 120 minute; cardiovascular and pulmonary disease. We inject 50 micro gram Dexmedetomodine subcutaneous in first group and we inject 100 milligram Ketamine subcutaneous in second group. We inject 5 milliliter normal saline subcutaneous in third group. We record mean duration of analgesia and score of pain by Visual Analog scale in 2, 4 and 8 hours after surgery. We record amount of narcotic drug and first request narcotic drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122520258N20**
Registration date: **2017-02-21, 1395/12/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-21, 1395/12/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Arak University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of topical Dexmedetomidine infiltration with subcutaneous Ketamine on postoperative pain in patients candidating abdominal hysterectomy under general anesthesia

Public title

Comparison effect of Topical Dexmedetomidine Infiltration with Subcutaneous Ketamine on postoperative Pain in surgery general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: abdominal hysterectomy; general anesthesia; 30-65 years; duration of surgery maximum

120 minute; ASA I and II Exclusion criteria: allergy for Dexmedetomidine and Ketamine; duration of surgery more than 120 minute; cardiovascular and pulmonary disease

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Arak, Sardasht, Basij Square, Payambar Azam Complex, Reaserch Center

City

Arak

Postal code

38149578558

Approval date

2016-11-23, 1395/09/03

Ethics committee reference number

IR.ARAKMU.REC.1395.297

Health conditions studied

1

Description of health condition studied

Abdominal hysterectomy

ICD-10 code

99.3 N

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

Mean duration of analgesia

Timepoint

2,4 and 8 hours after surgery

Method of measurement

Minute

2

Description

Score of pain

Timepoint

2,4 and 8 hours after surgery

Method of measurement

Visual Analogue Scale Questionnaire

3

Description

Amount of Narcotic drug

Timepoint

End of study

Method of measurement

miligeram

4

Description

Request narcotic drug

Timepoint

First time for request narcotic

Method of measurement

Minute after surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We inject 50 microgram Dexmedetomidine subcutaneous.

Category

Treatment - Drugs

2

Description

Intervention group: We inject 100 milligram Ketamine subcutaneous.

Category

Treatment - Drugs

3

Description

Control group: We inject 5 milliliter normal saline subcutaneous.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Maryam Shokrpour

Street address

Emam Khomeini street, Taleghani hospital

City

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Dr Alireza Kamali

Position

Anesthesiologist

Other areas of specialty/work

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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

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

medicine department

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