

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparing the effect of Ketamin ; Bupivacain and Dexmedetomidine intraperitoneal in controlling the pain after operation in patients are candidates for abdominal hysterectomy

Protocol summary

Study aim

Comparing the effect of Ketamin ; Bupivacain and Dexmedetomidine intraperitoneal in controlling the pain after operation in patients are candidates for abdominal hysterectomy

Design

This study is clinical trial and double blind.105 patients candidates for abdominal hysterectomy in Taleghani Hospital in Arak will inter this study.We will divide patients in 3 groups by simple randomization.Groups are parallel.

Settings and conduct

This study is clinical trial and double blind.105 patients candidates for abdominal hysterectomy in Taleghani Hospital in Arak will inter this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria:All patients are candidates for abdominal hysterectomy, ASA class 1 and 2, age 30 to 70 years, no sensitivity to drugs Exclusion criteria:Emergency patients ,dissatisfaction

Intervention groups

The first group will be injected with 0.5 to 0.7 microgram in kilogram dexmedetomidine intraperitoneal , the second group will be injected 20-15 milligram bupivacaine intraperitoneal and the third group will be injected 75-50 milligram ketamin intraperitoneal.

Main outcome variables

Pain, the amount of drug used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N130**

Registration date: **2020-01-20, 1398/10/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-20, 1398/10/30**

Update count: **0**

Registration date

2020-01-20, 1398/10/30

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Ketamin ; Bupivacain and Dexmedetomidine intraperitoneal in controlling the pain after operation in patients are candidates for abdominal hysterectomy

Public title

comparing the effect ofKetamin; Bupivacain and

Dexmedetomidine intraperitoneal in controlling the pain after operation in patients are candidates for abdominal hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients are candidates for abdominal hysterectomy
ASA class 1 and 2 Age 30 to 70 years No sensitivity to drugs

Exclusion criteria:

Emergency patients Dissatisfaction

Age

From **30 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in three groups A and B and C. 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

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B and C are available to analyzer and outcome assessor.

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

Postal code

3848176941

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.ARAKMU.REC.1397.265

Health conditions studied

1

Description of health condition studied

abdominal hysterectomy

ICD-10 code

N99.3

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

Pain

Timepoint

Recovery, 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

Visual analogue of pain

2

Description

Amount of drug used

Timepoint

24 hours after surgery

Method of measurement

Milligram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The first group will be injected with 0.5 to 0.7 microgram in kilogram dexmedetomidine intraperitoneal

Category

Treatment - Drugs

2**Description**

Intervention group2: The second group will be injected 20-15 milligram bupivacaine intraperitoneal.

Category

Treatment - Drugs

3**Description**

Intervention group3: The third group will be injected 75-50 milligram ketamin intraperitoneal.

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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Taleghani hospital, Emam Khomeini street

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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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Latest degree

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

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Full name of responsible person

Melika Akbari

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Shokrpour

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments