Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of remifentanil, Apotel (Paracetamol) and dexmedetomidine in postoperative pain control of abdominal hysterectomy candidates

Protocol summary

Study aim

Comparison of the effects of remifentanil, Apotel, and dexmedetomidine on pain control after abdominal hysterectomy.

Design

The present study is a double-blind, randomized, parallel-group clinical trial (using block randomization) conducted on 195 patients.

Settings and conduct

In this randomized double-blind clinical trial, patients scheduled for abdominal hysterectomy at Arak Sina Ashtiani Hospital will be randomly assigned using block randomization into three groups (A, B, and C). Blinding will be implemented by labeling the drug syringes and coding the patients. Finally, the study outcomes will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients scheduled for hysterectomy presenting to Sina Ashtiani Hospital; possession of a signed written informed consent; American Society of Anesthesiologists (ASA) Physical Status Classification, classes I and II. Exclusion criteria: Presence of systemic diseases including renal, hepatic, cardiovascular disorders, hypertension, diabetes, or malignancy; history of substance abuse or chronic analgesic consumption; presence of known hypersensitivity to any of the study drugs and a history of seasonal allergy.

Intervention groups

In intervention group 1, patients will receive 1 g Apotel, 16 mg dexamethasone, 16 mg ondansetron, and 10 mg morphine. In intervention group 2, patients will receive 16 mg dexamethasone, 16 mg ondansetron, 10 mg morphine, and 30 µg dexmedetomidine. In intervention group 3, patients will receive 16 mg dexamethasone, 16 mg ondansetron, 10 mg morphine, and 1 g remifentanil.

Main outcome variables

Duration of analgesia, mean arterial pressure, heart rate, arterial oxygen saturation, opioid consumption, pain score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N45**
Registration date: **2025-10-09, 1404/07/17**
Registration timing: **prospective**

Last update: **2025-10-09, 1404/07/17**
Update count: **0**

Registration date

2025-10-09, 1404/07/17

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-17, 1404/07/25

Expected recruitment end date

2026-01-15, 1404/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of remifentanil, Apotel (Paracetamol) and dexmedetomidine in postoperative pain control of abdominal hysterectomy candidates

Public title
Comparison of the effects of remifentanil, Apotel, and dexmedetomidine on pain control after abdominal surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients scheduled for hysterectomy presenting to Sina Ashtiani Hospital. Having a written informed consent. American Society of Anesthesiologists (ASA) Physical Status Classification I, II

Exclusion criteria:
Presence of systemic diseases including renal, hepatic, cardiovascular disorders, hypertension, diabetes, or malignancy. Having a history of substance abuse or chronic analgesic consumption. Presence of known hypersensitivity to the study drugs and seasonal allergy.

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **195**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned to three intervention groups in order of arrival and based on a randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. A block randomization method with blocks of 6 will be used to allocate the samples. Thus, using the block random number generation software, a randomization sequence proportional to the required sample size will be generated for the three groups. Initially, all the cases in which the 3 letters A, B, and C can be arranged together in a block of 6 are performed. Then, a block is randomly selected from the blocks by placement, and the arrangement pattern in that block will be used to allocate the participants. Then this block is placed in the main container and another block will be selected again. All these steps will be performed with a software called Sealed Envelope. Concealment will also be observed using this method. The concept of concealment is to make the assignment of individuals to groups unpredictable. In fact, the researcher will not be able to predict which group the next person will be placed in.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted in a double-blind design. None of the patients will be aware of the type of drug they receive. The drugs will be administered to the patients by the anesthesiologist. The injection syringes will be labeled with the patient’s medical record number, without disclosure of their contents; therefore, patients will not know the type of injectable medication. The assigned intern responsible for recording outcomes will not be aware of the patients’ group allocation, will evaluate them based on their medical record number, and will hand over the collected data to the corresponding anesthesiologist. Consequently, the intern will have no knowledge of the patients’ group assignment or prescribed drugs.

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
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2025-05-04, 1404/02/14

Ethics committee reference number
IR.ARAKMU.REC.1404.048

Health conditions studied

1

Description of health condition studied
Postoperative pain control

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain score
Timepoint
In the recovery room and 2, 4, 8, 12 hours after surgery
Method of measurement
Visual analog scale

2

Description
Pain relief period
Timepoint
24 hours after surgery.
Method of measurement
History and physical examination

3

Description
Opioid consumption
Timepoint
24 hours after surgery.
Method of measurement
Patient file

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
At the beginning of surgery and every 15 minutes until the end of surgery.
Method of measurement
NIBP monitoring device

2

Description
Heart rate
Timepoint
At the beginning of surgery and every 15 minutes until the end of surgery.
Method of measurement
Cardiac monitoring device

3

Description
Arterial blood oxygen saturation
Timepoint
At the beginning of surgery and every 15 minutes until the end of surgery.
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Intervention group 1: Patients will receive 1 g Apotel, 16 mg dexamethasone, 16 mg ondansetron, and 10 mg morphine.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients will receive 16 mg dexamethasone, 16 mg ondansetron, 10 mg morphine, and 30 µg dexmedetomidine.
Category
Treatment - Drugs

3

Description
Intervention group 3: Patients will receive 16 mg dexamethasone, 16 mg ondansetron, 10 mg morphine, and 1 g remifentanil.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Rezaei Ashtiani Hospital
Full name of responsible person
Dr. Maryam Shekarpour
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Sina Rezaei Ashtiani Hospital, Basij Square, Sardasht, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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Full name of responsible person
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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
Associate professor

Latest degree
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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

No - There is not 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

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2026/2/21 to 2029/2/21 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

Academic researchers and university faculty members, following initial contact via message or email with the relevant professor, may request access to and use of data from Dr. Alireza Kamali. Dr. Alireza Kamali, Phone: +98-918-162-2810, Email: alikamaliir@yahoo.com, Address: Department of Education, Valiasr Hospital, Arak, Iran

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

Letter writing should be done with professors and universities.

Comments