Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparing the effect of intravenous combined Paracetamol (Apotel) and Ketamine on postoperative nausea and vomiting in patients candidating hysterectomy

Protocol summary

Study aim

Comparison of the effects of ketamine and intravenous Epotel on reducing nausea and vomiting after hysterectomy surgeries.

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 114 patients. In this study, randomization will be done using the Sealed Envelope software and using the block method in blocks of 3 and 6.

Settings and conduct

The current study is a randomized clinical trial study that will be performed on 114 patients who are candidates for hysterectomy surgery (abdominal and laparoscopic). The environment of this project is Taleghani Hospital of Arak University of Medical Sciences. Since the study is designed in a double-blind manner, the patients will be randomly assigned to the receiving groups of ketamine, intravenous Apotel, and placebo, and the outcome assessors and clinical caregivers are not aware of the medication received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidates for elective hysterectomy, general anesthesia, receiving opioids after surgery, age 25 to 65 years.Exclusion criteria: allergy to any of the drugs used in the study, history of mental illnesses

Intervention groups

After induction of anesthesia in all participating patients, in the first intervention group, in the last 15 minutes of the operation, an amount of one gram of Aptotel is slowly injected intravenously. In the second intervention group, in the last 15 minutes of the operation, the amount of 0.15 mg/kg The drug is injected slowly and intravenously. In the control group, 30 cc of normal saline is injected.

Main outcome variables

nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221111056474N1**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

پیروزی Pirouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 6304

Email address

parandpirouzi228@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of intravenous combined Paracetamol (Apotel) and Ketamine on postoperative nausea and vomiting in patients candidating hysterectomy

Public title
Comparison of the effects of ketamine and paracetamol on nausea and vomiting after hysterectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate patients for elective hysterectomy General anesthesia Receiving opioids after surgery Age 25 to 65 years

Exclusion criteria:
Allergy to any of the drugs used in the study History of mental illnesses

Age
From **25 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to two intervention groups and one control group based on the randomization sequence that will be generated in advance, in the order of arrival, and this sequence is unpredictable and its arrangement is completely random. To allocate the samples, the block randomization method will be used with the size of 3 and 6 blocks in such a way that by using the Sealed Envelope software to generate random numbers in the block method, the randomization sequence will be produced according to the required sample size for the three groups. In the beginning, all the modes in which 3 letters A, B and C can be arranged together in blocks of 3 and 6 are produced and randomly and by placing among the blocks, a block is selected and the pattern of arrangement in that block is for allocation. Patients will be used, then this block will be placed in the main container and another block will be selected again. 3 and 6 blocks will all be in one container.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. To observe the blinding of the first type, the patients do not know the type of medicine received. In all three groups, the same syringes are used, and the patient and the person in charge of the project do not know about their contents. In order to observe the blinding of the second type, the injection drugs were drawn in separate syringes by the respected anesthetist, and the person in charge of the project (a student) was drawn from the contents. It has no information.

Placebo
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
Payambar azam complex, Basij Sq., Sardasht Town

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2022-07-03, 1401/04/12

Ethics committee reference number
IR.ARAKMU.REC.1401.104

Health conditions studied

1

Description of health condition studied
Nausea and vomiting after hysterectomy

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Nausea and vomiting

Timepoint
4, 6, 12, and 24 hours after hysterectomy surgery

Method of measurement
Post-operative nausea and vomiting scoring table

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: After induction of anesthesia in all patients, in the first intervention group, in the last 15 minutes of the operation, an amount of one gram of Apotel (Kobel Daru-Iran) is injected as a slow intravenous injection.
Category
Treatment - Drugs

2

Description
Intervention group 2: After induction of anesthesia in all patients, in the second intervention group, ketamine (Darman yab -Iran) is injected intravenously at a rate of 0.15 mg/kg in the last 15 minutes of the operation.
Category
Treatment - Drugs

3

Description
Control group: After induction of anesthesia in all patients, in the control group, 30 cc of normal saline is slowly injected intravenously in the last 15 minutes of the operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Parand Pirouzi
Street address
Imam khomeini Ave.
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3816149369
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+98 86 3277 6035
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mehdi Salehi
Street address
Payambar azam complex, Basij Sq., Sardasht Town
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research@arakmu.ac.ir
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
Parand Pirouzi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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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