Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of injectable Acetaminophen with Ketamine injected by Morphine pump on reducing acute pain after surgery

Protocol summary

Study aim
Determining and comparing the effect of injectable Acetaminophen with injectable Ketamine by Morphine pump on reducing acute pain after surgery

Design
Double-blind clinical trial with control group, with parallel groups, phase 3 number of 20 on 60 patients. Allocation of samples to intervention groups is done by doctor's order.

Settings and conduct
This study is conducted on patients referred to Shahid Rajaee Hospital who are candidates for various surgeries according to the doctor's orders. Based on the doctor's diagnosis, the patient enters one of the three test groups A (1 mg of Acetaminophen plus 10 mg of Morphine in 100 cc Normal saline at a rate of 4 drops per minute), experimental group B (1 mg of Ketamine plus 10 mg of Morphine in 100 cc of Normal saline at a rate of 4 drops per minute) and the control group (10 mg of Morphine in 100 cc of Normal saline with the speed is 4 drops per minute). The participant and outcome evaluator are blind

Participants/Inclusion and exclusion criteria
Inclution criteria: Patients aged 15 to 60 who are candidates for surgery Exclusion criteria: Long-term use of Corticosteroids, Antihistamines and painkillers Allergy to Acetaminophen, Ketamine and Morphine

Intervention groups
Test group A (1 mg of Acetaminophen plus 10 mg of Morphine in 100 cc of Normal saline at a rate of 4 drops per minute), test group B (1 mg of Ketamine plus 10 mg of Morphine in 100 cc of Normal saline at a rate of 4 drops per minute) and the control group (10 mg of Morphine in 100 cc of Normal saline at a rate of 4 drops per minute)

Main outcome variables
The amount of pain after the operation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230827059269N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-24, 1402/07/02**
Update count: **0**

Registration date
2023-09-24, 1402/07/02

Registrant information
Name
Majid Golrezaei
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-11, 1402/06/20

Expected recruitment end date
2024-01-10, 1402/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of injectable Acetaminophen with Ketamine injected by Morphine pump on reducing acute pain after surgery

Public title
Comparison of the effect of injectable Acetaminophen with Ketamine injected on reducing acute pain after surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 15 to 60 are candidates for surgery
Exclusion criteria:
History of surgery History of smoking, alcohol and drug abuse Chronic mental and physical illness (schizophrenia, diabetes, etc.) Vision and hearing problems and other disabilities Long-term use of corticosteroids, antihistamines, narcotics and painkillers Allergy to acetaminophen, ketamine, morphine Pregnancy and breastfeeding and abortion less than 3 months
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind type of experiment, which will be blind for the people participating in the study and evaluating the outcome. In the consent form to participate in the study, it is written for the patient that his presence does not necessarily mean intervention but may be included in the control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of qazvin University of Medical Sciences
Street address
Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd,Qazvin
City
Qazvin
Province
Qazvin
Postal code
3413996134
Approval date
2022-02-15, 1400/11/26
Ethics committee reference number
IR.QUMS.REC.1400.458

Health conditions studied

1

Description of health condition studied
Acute pain after surgery
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
The amount of pain after the operation
Timepoint
3, 6 and 12 hours after the operation
Method of measurement
Using a ruler-like grading system (Visual Analog Scale) from 0 (no pain) to 10 (the most severe pain imaginable)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In test group A (Acetaminophen drug), after surgery, the patient enters the recovery department, and after fully regaining consciousness and expressing pain, the injection drug Acetaminophen with a dose of 1 mg by an infusion pump by an anesthesiologist as a pain reliever. Analgesic plus 10 mg of Morphine in 100 cc of Normal saline is injected intravenously to the patient at a rate of 4 drops per minute to reduce pain.
Category
Treatment - Drugs

2

Description
Intervention group: In test group B (Ketamine drug), after surgery, the patient enters the recovery department, and after fully regaining consciousness and expressing pain, the injection drug Ketamine with a dose of 1 mg by an infusion pump by an anesthesiologist as a pain reliever. Analgesic plus 10 mg of Morphine in 100 cc of Normal saline is injected intravenously to the patient at a rate of 4 drops per minute to reduce pain.

Category
Treatment - Drugs

3

Description
Control group: In the placebo group, after the surgery, the patient enters the recovery department, and after regaining consciousness and expressing pain, 10 mg of Morphine in 100 cc of Normal saline is injected intravenously at a rate of 4 drops per minute to reduce pain.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital
Full name of responsible person
Majid Golrezaei
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Majid Golrezaei
Position
Resident
Latest degree
Medical doctor
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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