

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 Rajaei 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

Inclusion 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)

Phone

+98 28 3333 6001

Email address

m.golrezaei@gmail.com

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

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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

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