

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of dextromethorphan with ketamine in relieving pain after abdominal surgery in Islamic Azad University hospitals in 2021-2022

Protocol summary

Study aim

Comparing the effect of dextromethorphan with ketamine in relieving pain after abdominal surgery in Islamic Azad University hospitals in 2021-2022

Design

Phase 2 double-blind randomized clinical trial with a sample size of 46 patients

Settings and conduct

In this study, which was conducted in the form of a clinical trial, 46 patients who were candidates for abdominal surgery, who were randomly selected from Bu Ali Hospital, were included in the study and randomly using block randomization, accessible and double-blind, that neither people nor technicians who It records people's information, they don't know about the type of drug they received, they were placed in two groups receiving ketamine and dextromethorphan. He does not know, he records the information and at the end of the work, the student collected the recorded information. Demographic information of patients such as age, gender and clinical information such as type of surgery, pain intensity before surgery, one hour, 4 hours, 8 hours and 12 hours after recovery were recorded. After the operation, at the time of requesting analgesia, he was treated with intravenous meperidine, and at the time of requesting analgesia and expressing pain, pain intensity was recorded and compared using the VAS method. Then the obtained information was entered into SPSS software version 26 and the result and statistical analysis was done based on the nature of the variables.

Participants/Inclusion and exclusion criteria

Entry requirements: patients who are candidates for abdominal surgery; lack of drug sensitivity to the drugs used; ASA one and two. Exit conditions: BMI less than 20 to more than 30; patients with age above 70 years old; reluctance to continue participation; occurrence of problems during surgery.

Intervention groups

Two groups receiving ketamine and dextromethorphan

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230303057595N1**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **retrospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Shahin Rashvand Haranaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3457 1005

Email address

rashvandshahin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

2022-03-21, 1401/01/01
Actual recruitment end date
2022-03-21, 1401/01/01
Trial completion date
2022-03-21, 1401/01/01

Scientific title
Comparing the effect of dextromethorphan with ketamine in relieving pain after abdominal surgery in Islamic Azad University hospitals in 2021-2022

Public title
Comparing the effect of dextromethorphan with ketamine in relieving pain after abdominal surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for abdominal surgery Lack of drug sensitivity to the drugs used ASA 1,2
Exclusion criteria:
BMI less than 20 to more than 30 Patients with age above 70 years Unwillingness to continue participation Occurrence of problems during surgery

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **46**
Actual sample size reached: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly assigned to two groups receiving ketamine and dextromethorphan using block randomization and available and double-blind, in which neither the subjects nor the technician who records the information of the subjects know the type of drug received.

Blinding (investigator's opinion)
Double blinded

Blinding description
People do not know which treatment group they are placed in, and also an impartial technician who does not know the type of treatment of each person records the information and at the end of the student's work, she collected the recorded information.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Islamic Azad University of Medical Sciences

Street address

Tehran, Doktor Shariati St., Golhak Do Rahi, Amir Pabarja St., Aine Blvd., Corner of Gol Yakh St., Headquarters Building of Tehran Islamic Azad University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2022-09-19, 1401/06/28

Ethics committee reference number

IR.IAU.TMU.REC.1401.201

Health conditions studied

1

Description of health condition studied

Abdominal surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain by Visual Analogue Scale

Timepoint

Before the operation, one hour, 4 hours, 8 hours and 12 hours after recovery

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ketamine receiving group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University Hospitals (Boali, Amirul Mominin, Farhikhtegan)

Full name of responsible person

Giti Dehghan Manshad

Street address

Tehran, Doktor Shariati St., Golhak Do Rahi, Amir Pabarja St., Aine Blvd., Corner of Gol Yakh St., Headquarters Building of Tehran Islamic Azad University of Medical Sciences

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Email

rashvandshahin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

Tehran, Doktor Shariati St., Golhak Do Rahi, Amir Pabarja St., Aine Blvd., Corner of Gol Yakh St., Headquarters Building of Tehran Islamic Azad University of Medical Sciences

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Shahin Rashund Hranki

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available