Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the incidence of postoperative delirium in patients with colorectal cancer undergoing elective surgery after intervention with ketamine and/or melatonin compared to the control group

Protocol summary

Study aim

Determining the frequency and severity of postoperative delirium in patients undergoing colorectal surgery who receiving ketamine and melatonin.

Design

Clinical trial with a control group, with parallel groups,double-blind, randomized, phase 3on60 patients.The rand function of Excel software was used for randomization.

Settings and conduct

This research will be conducted at Imam Khomeini Hospital in Tehran in 1401 and 1402.This study will be conducted as a clinical intervention using drugs and placebo and double blind.Patients will be grouped using random numbers and placed in a sealed envelope.The person responsible for registering the patient's symptoms,the person responsible for statistical analysis,and the operating room nurse do not know about the patient's grouping.

Participants/Inclusion and exclusion criteria

Inclusion : Candidates for elective colorectal cancer surgery The age between 18-70 Patient consent Non-participation of the patient in another drug clinical trial Exclusion: Emergency surgeries Lack of consent Multiple trauma patients Age> 70 Candidate patients for multiple surgeries Chronic renal failure patients (GFR <20% of normal) history of ascites or liver cirrhosis history of anaphylactic medications. heart failure (EF<25%) ischemic heart disease

Intervention groups

Patients are randomly divided into 4 equal groups: The first group, 10 mg melatonin the night before the operation and placebo during surgery. The second group received a placebo (oral pill) the night before surgery and bolus dose of 50 mg of ketamine after anesthesia induction. The third group received 10 mg of melatonin the night before surgery and bolus dose of 50 mg of ketamine after anesthesia induction. Fourth group is the control group that receives placebo (oral pill) the night before surgery and placebo (normal saline) after anesthesia induction.

Main outcome variables

postoperative delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009886N2**
Registration date: **2023-03-07, 1401/12/16**
Registration timing: **prospective**

Last update: **2023-03-07, 1401/12/16**
Update count: **0**

Registration date

2023-03-07, 1401/12/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

02161192663-02161192828

Email address

mohammady_mm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-08, 1401/12/17

Expected recruitment end date

2023-08-10, 1402/05/19

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the incidence of postoperative delirium in patients with colorectal cancer undergoing elective surgery after intervention with ketamine and/or melatonin compared to the control group

Public title
postoperative delirium in patients with colorectal cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for elective colorectal cancer surgery Patient age between 18 and 70 years Patient consent to participate in the plan Non-participation of the patient in another drug clinical trial
Exclusion criteria:
Emergency surgeries Non-consent Multiple trauma cases Age more than 70 years Candidate patients for multiple surgeries (or second or third surgery cases) Chronic renal failure patients (or single kidney patients or patients with GFR less than 20% of normal) Patients with a history of ascites or liver cirrhosis Patients with a history of anaphylactic reactions to melatonin, ketamine, or propofol Patients with heart failure (cardiac ejection fraction less than 25%) Patients with ischemic heart disease
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization lists are computer-based by a statistician and the participants and project managers will be completely unaware (blind) about the intervention and control groups. Placebo and melatonin pills are identical. Placebo pills are produced by Faculty of Pharmacy, Tehran University of medical science. The concealment of supplements will be done by a third person, and the participants and investigators are not aware of the groups' assignments until the end of analysis.
Blinding (investigator's opinion)
Double blinded
Blinding description
The pills are inside a sealed envelope with a specific code. Syringes containing ketamine or normal saline (as placebo) are stored in the operating room refrigerator and coded.Both the researcher and the nurse are unaware of the relationship between the code and the capsule type (melatonin or placebo/ketamine or placebo). Only the main researcher and the physician responsible for the patient's anesthesia (who are not involved in sampling or recording the patients' information) are aware of the codes and contents of the drug or syringe envelope.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshavarz Boulevard, Porsina Street, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1416634793
Approval date
2022-02-14, 1400/11/25
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.374

Health conditions studied

1

Description of health condition studied
Colon cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

Primary outcomes

1

Description
postoperative delirium
Timepoint

12 and 24 hours after surgery

Method of measurement

Confusion Assessment Method-Intensive Care Unit

Secondary outcomes

empty

Intervention groups

1

Description

Control group: They will receives a placebo (oral pill) the night before the operation and a placebo (normal saline solution) after induction of anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group 1: The night before the operation, 10 mg of melatonin and placebo during the operation.

Category

Treatment - Drugs

3

Description

Intervention group 2: The night before the operation, they receive a placebo (oral pill) and an intravenous bolus dose of 50 mg of ketamine after induction of anesthesia.

Category

Treatment - Drugs

4

Description

Intervention group 3: The night before the operation, they receive 10 mg of melatonin and an intravenous bolus dose of 50 mg of ketamine after induction of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hopsital

Full name of responsible person

Mostafa Mohammadi

Street address

Keshavarz BlvD, Dr Qarib St

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1419733141

Phone

+98 21 6119 0000

Email

mohammady_mm@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology.

Street address

North Kargar St., intersection of Keshavarz Blvd

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1419733141

Phone

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icedu@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mostafa Mohammadi

Position

Professor of critical care

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Keshavarz Blvd., Dr. Gharib St

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mostafa Mohammadi
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Professor of critical care
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared.
When the data will become available and for how long
access starting after publication
To whom data/document is available
Our data will only be available for people working in academic institutions.
Under which criteria data/document could be used
Our data of the study will only be accessible for conducting Meta-analysis.
From where data/document is obtainable
To access the required data, the researchers can contact Dr. Mostafa Mohammadi: Email address:mohammady_mm@tums.ac.ir
What processes are involved for a request to access data/document
The applicants should provide a description of the propose of their Meta-analysis. That request will be assessed, and if we agree to the request, the data will be emailed.
Comments