Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Comparative Evaluation of the Impact of Cannabidiol Administration Versus Non-Administration on Sleep Quality and Pain Outcomes in Patients Undergoing Intermediate Elective Abdominal Surgery

Protocol summary

Study aim

Comparison of the effect of administering versus not administering cannabidiol on sleep quality and pain relief in patients undergoing intermediate elective abdominal surgery.

Design

This clinical trial is a randomized, parallel-group, double-blind study with a control group, in which participants will be assigned to one of the two groups using a simple online randomization method. The study is a Phase II trial involving 50 patients.

Settings and conduct

The target population consists of patients referred to Imam Khomeini Center for elective intermediate abdominal surgery. Participants will be randomly assigned to one of the two groups using an online randomization method. The study is double-blind, with both the patient and the outcome assessor evaluating sleep quality and pain being unaware of whether cannabidiol or sterile water has been administered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing intermediate elective abdominal surgery, aged 18–65 years, American Society of Anesthesiologists (ASA) class II/III, and willing to provide informed consent. Exclusion criteria: Patients with substance abuse, a history of psychiatric disorders, or sleep disturbances.

Intervention groups

Intervention group: Administration of oral solution (as drops) of cannabidiol at a concentration of 100 mg/mL and a dose of 25 mg (equivalent to 0.25 mL of the solution) as a single dose at the start of induction before the surgical procedure, which the patient will orally ingest. The solution brand is CannaPure CBD Oral Solution, manufactured by CannaPure Pharmaceuticals Ltd. Control group: Administration of an oral solution (drops) of sterile water at the start of anesthesia induction before the surgical procedure, which the patient will orally ingest.

Main outcome variables

Patients' sleep quality and Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058586N12**
Registration date: **2026-01-03, 1404/10/13**
Registration timing: **prospective**

Last update: **2026-01-03, 1404/10/13**
Update count: **0**

Registration date

2026-01-03, 1404/10/13

Registrant information

Name

Nasim Sohrabifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 938 229 6766

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Evaluation of the Impact of Cannabidiol Administration Versus Non-Administration on Sleep Quality and Pain Outcomes in Patients Undergoing Intermediate Elective Abdominal Surgery

Public title

The effect of cannabidiol on sleep quality and pain reduction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients Undergoing Intermediate Elective Abdominal Surgery Age between 18 and 65 years American Society of Anesthesiologists (ASA class) II/III Patient satisfaction

Exclusion criteria:

Addicted patients Patients with a history of psychiatric disorders and sleep disturbances

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The website www.Randomization.com will be used for randomization (online, simple randomization). After determining the number of intervention groups, which are two groups, and the required number in each of these groups, the website will provide us with a random table of numbers that will represent the patient's number. Then the random sequence is available to the researcher. The researcher performs the desired intervention based on the order in which the participants entered the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind trial, such that: patients will not know whether they are receiving cannabidiol or a placebo (sterile water). However, the study groups will be explained to the patients when obtaining informed consent. The person who measures and records outcomes, including pain levels and sleep quality, will also be unaware of the allocation of drug or placebo to the patients. The drug and placebo will be prepared in identical containers and packaging and will be coded; only the pharmacist, who does not participate in data analysis, will keep the codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Imam Khomeini Hospital Complex, Tehran University of Medical Sciences

Street address

Ethics Committee of the Imam Khomeini Hospital Complex, Office of the Deputy for Research, southwest wing, Imam Khomeini Hospital Complex, End of Keshavarz Boulevard.

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2025-12-02, 1404/09/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1404.405

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

F51.8

ICD-10 code description

Other sleep disorders not due to a substance or known physiological condition

2

Description of health condition studied

Postoperative Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Post operative sleep quality

Timepoint

Once after the intervention (after recovery).

Method of measurement

Using the Richards-Campbell Sleep Questionnaire (RCSQ)

2

Description

Post operative pain

Timepoint

At four time points: namely 1 hour, 2 hours, 4 hours, and 8 hours after the intervention.

Method of measurement

Visual Analog Survey Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of an oral solution (as drops) of cannabidiol at a concentration of 100 mg/mL and a dose of 25 mg (equivalent to 0.25 mL of the solution) will be given as a single dose at the start of anesthesia induction before the surgical procedure, which the patient will orally ingest. The solution brand is CannaPure CBD Oral Solution, manufactured by CannaPure Pharmaceuticals Ltd.

Category

Prevention

2

Description

Control group: Administration of an oral solution (drops) of sterile water will be given as a single dose at the start of anesthesia induction before the surgical procedure, which the patient will orally ingest.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Kasra Karvandian

Street address

Imam Khomeini Hospital Complex, Keshavarz blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

Research and Technology Deputy Office, 6th Floor, University Central Organization, corner of Ghods Street, Keshavarz Boulevard

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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

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

Kasra Karvandian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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