

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

A comparative study of the effect of melatonin, clonidine or gabapentin on reducing the preoperative anxiety and postoperative pain in patients undergoing laparoscopic cholecystectomy in Shariati Hospital in 1393

Protocol summary

Summary

Objective: Comparing the effect of melatonin, clonidine or gabapentin on reducing the preoperative anxiety and postoperative pain in patients undergoing laparoscopic cholecystectomy. Patients referred to Shariati Hospital in 1393 for laparoscopic cholecystectomy who did not have a history of congenital heart diseases, heart valve diseases, liver or kidney diseases, psychological disorders, opioid addiction, uncontrolled hypertension, and those without with verbal or communication difficulties will be included in the study. In a randomized double-blind placebo-controlled clinical study, 88 patients undergoing laparoscopic cholecystectomy under general anesthesia will be enrolled and randomly assigned to one of the four study groups: clonidine (C), melatonin (M), gabapentin (G), or placebo (P). 120 minutes before inducing anesthesia, patients will be administered oral clonidine (0.2 mg), melatonin (6 mg), gabapentin (600 mg), or placebo, respectively. In order to alleviate the pain, morphine will be administered using the PCA instrument. Preoperative anxiety, changes in the vital signs after induction of anesthesia, total dosage of the intraoperatively administered opioid, Bispectral index (BIS), morphine dosage within 24 h of the operation, the first time of requesting morphine post-operation, and postoperative nausea and vomiting (PONV) will be recorded and compared for all patients. The level of pain will also be accessed and recorded using a 10-score visual analogue scale (VAS) 1 h, 2 h, 6 h, 12 h, and 24 h after the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041217231N1**
Registration date: **2014-07-01, 1393/04/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-01, 1393/04/10

Registrant information

Name

Vahideh Sadat Hosseini

Name of organization / entity

Shariati hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2373

Email address

hghasemi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-06-01, 1393/03/11

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of melatonin, clonidine or gabapentin on reducing the preoperative anxiety and

postoperative pain in patients undergoing laparoscopic cholecystectomy in Shariati Hospital in 1393

Public title

The effect of melatonin, clonidine, and gabapentin on reducing the preoperative anxiety and postoperative pain in patients undergoing laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients scheduled for elective laparoscopy cholecystectomy; Signing the informed written consent; Exclusion Criteria:History of congenital heart diseases; History of heart valve diseases; History of liver or kidney diseases; History of psychological disorders; Opioid addiction; Uncontrolled hypertension; Patients with verbal or communication difficulties

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committee - TUMS

Street address

Tehran University of Medical sciences

City

Tehran

Postal code

Approval date

2013-08-04, 1392/05/13

Ethics committee reference number

92/130/912/5

Health conditions studied

1

Description of health condition studied

Epigastric Pain

ICD-10 code

R10.1

ICD-10 code description

Pain localized to upper abdomen

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety NOS

Primary outcomes

1

Description

Anxiety

Timepoint

The night before the surgery and when entering the operating room

Method of measurement

STAI questionnaire

2

Description

Pain

Timepoint

2 h before and 1 h, 2 h, 6 h, 12 h, and 24 h after the surgery

Method of measurement

VAS, PCA

Secondary outcomes

empty

Intervention groups

1

Description

Placebo, 120min before surgery

Category

Placebo

2

Description

melatonin 6mg, 120min before surgery

Category

Treatment - Drugs

3

Description

clonidine 0.2mg, 120min before surgery

Category

Treatment - Drugs

4

Description

Gabapentin 600mg, 120min before surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Vahideh Sadat Hosseini

Street address

Shariati hospital, North kargar st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Keshavarz Bolvard, Ghods St

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shariati Hospital

Full name of responsible person

Vahideh Sadat Hosseini

Position

Resident of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty