

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Randomized double-blinded clinical trial: The effect of premedication with Valiflore on preoperative anxiety compared with placebo in patients undergoing elective laparoscopic cholecystectomy

Protocol summary

Summary

The purpose of this clinical trial is the evaluation of the effect of premedication with Valiflore compared with placebo on preoperative anxiety in patients undergoing elective laparoscopic cholecystectomy. This investigation is a double-blinded randomized clinical trial on eighty patients aged 20-55 years; classified as American Society of Anesthesiologists physical status I and II who were undergoing elective surgical laparoscopic cholecystectomy. Patients with a history of anxiety and other mental disorders, those consuming antidepressant, sedative, analgesic and anti-epileptic drugs and patients with numerical rating scale for anxiety less than one, were excluded from the study. Patients were randomly divided into two groups control (n= 40) and intervention (n=40) using a computer generated randomization list. Both the interventionist and the patients were blinded to group assignment. Two hours before surgery, patients are brought to a quiet room in the operating room. Patients in the control group receive a placebo tablet and patients in the intervention group receive a Valiflore tablet orally two hours before surgery. The placebo and active form of drug are identical in appearance. Ramsey Sedation Scale and Numeric Rating Scale are measured before, 15 minutes, 30 minutes, 60 minutes, 90 minutes and 120 minutes after administration of premedication and Digit Symbol Substitution Test is measured 30 minutes and 90 minutes after extubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404115175N13**

Registration date: **2014-05-18, 1393/02/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Ali Movafegh

Name of organization / entity

Dr. Shariati Hospital

Country

Iran (Islamic Republic of)

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+98 21 8490 2373

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-19, 1393/02/29

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized double-blinded clinical trial: The effect of premedication with Valiflore on preoperative anxiety compared with placebo in patients undergoing elective laparoscopic cholecystectomy

Public title

The effect of premedication with Valiflore on preoperative anxiety

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Patients at the age of 20-55; American Society of Anesthesiologists class I, II; Patients undergoing surgical laparoscopic cholecystectomy.
Exclusion criteria: Patients with a history of anxiety disorders and other mental disorders; Patients with a drug history of sedative drugs; Analgesic; Anti-depressant and anti-seizure; Patients with Numerical Rating Scale for anxiety $\leq$ less than 1.

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Ethics Committee, Faculty of Medicine

Street address
Faculty of Medicine, Tehran University of Medical Sciences and Health Care

City
Tehran

Postal code

Approval date
2012-12-20, 1391/09/30

Ethics committee reference number
130/2366/91/3

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Anxiety

Timepoint
Before administration of premedication, 15 minutes, 30 minutes, 60 minutes, 90 minutes and 120 minutes after administration of premedication

Method of measurement
Numeric Rating Scale

Secondary outcomes

1

Description
Sedation

Timepoint
Before administration of premedication, 15 minutes, 30 minutes, 60 minutes, 90 minutes and 120 minutes after administration of premedication

Method of measurement
Ramsey Sedation Scale

2

Description
Duration of anesthesia

Timepoint
First minute of anesthesia, first minute of recovery

Method of measurement
Time in minute

3

Description
Duration of surgery

Timepoint
First minute of starting surgery, minute of finishing surgery

Method of measurement
Time in minute

4

Description
Duration of departure time of recovery

Timepoint
First minute of entering recovery, minute of departure of recovery

Method of measurement
Time in minute

Intervention groups

1

Description

Patients in the intervention group (number=40) receive a valiflore tablet orally 2 hours before the surgery.

Category

Prevention

2

Description

Patients in the control group (number=40) receive a placebo tablet orally 2 hours before the surgery. placebo tablet is similar to the original drug in color, odor and shape.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ali Shariati Hospital

Full name of responsible person

Dr. Ali Movafegh

Street address

Dr. Ali Shariti Hospital, North karegar Ave, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Shahin Akhoundzade

Street address

Tehran University of Medical Sciences, Tehran, Iran

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 and Health Services

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Movafegh

Position

Professor

Other areas of specialty/work

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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