Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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
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Iran (Islamic Republic of)
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movafegh@sina.tums.ac.ir

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 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/د

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 anesthetia, 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
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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
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Person responsible for updating data

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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