

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Compare the anti-anxiety effect of cardamom with oral diazepam on preoperative anxiety in patients undergoing orthopedic surgery

Protocol summary

Study aim

The aim of this study was to compare the anti-anxiety effect of cardamom with oral diazepam on preoperative anxiety in patients undergoing orthopedic surgery in Imam Ali Hospital in Bojnourd.

Design

The present study Will be a randomized, one blind, clinical trial of 48 patients (16 Cardamom Extract, 16 oral diazepam and 16 control group) undergoing orthopedic surgery in Imam Ali Hospital in Bojnourd. Patients will initially assessed for inclusion criteria and Exclusion criteria. Then, eligible patients are selected by available sampling method and will be randomly assigned to three groups using the random number table.

Settings and conduct

The present study Will be a randomized, one blind, clinical trial of 48 patients (16 Cardamom Extract, 16 oral diazepam and 16 control group) undergoing orthopedic surgery in Imam Ali Hospital in Bojnourd.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of mental illness; non-use of psychiatric and psychosocial drugs; sedative drugs; non-use of narcotic and absence of acute and chronic disease; Exclusion criteria: Use of anti-anxiety or sedative after the start of the study; and dissatisfaction with the presence of the study

Intervention groups

The night before the surgery, the patients in the Cardamom Extract group will receive 10 drops (equivalent to 250 mg) of Cardamom Extract, dissolved in 50 cc of urban water, the diazepam group also will receive 5 mg oral diazepam tablets plus 50 cc of urban water and the control group will receive only 50 cc of urban water

Main outcome variables

The level of anxiety of the patients at 21 o'clock, one night before surgery will assessed by the researcher's assistance (researcher's assistance will be unaware to the intervention and control groups) for pretest and one

hour before the operation begins Surgery for the post-test will be measured with the Spielberg tool.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170921036302N1**

Registration date: **2017-12-26, 1396/10/05**

Registration timing: **retrospective**

Last update: **2017-12-26, 1396/10/05**

Update count: **0**

Registration date

2017-12-26, 1396/10/05

Registrant information

Name

sadigheh Khalili Shomia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8328

Email address

khalilis@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-10-02, 1396/07/10

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

2017-10-02, 1396/07/10

Actual recruitment end date

2017-11-01, 1396/08/10
Trial completion date
empty

Scientific title
Compare the anti-anxiety effect of cardamom with oral diazepam on preoperative anxiety in patients undergoing orthopedic surgery

Public title
The anti-anxiety effect of cardamom with oral diazepam on preoperative anxiety in patients undergoing orthopedic surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients are awake Anesthesia risks class 1 and 2 of the American Society for Anesthesiology (ASA) Have no history of mental illness Lack of psychiatric, sedation drugs and narcotics Non-acute and chronic illness.
Exclusion criteria:
Taking anti-anxiety or sedation after the onset of the study Dissatisfaction with the presence of the study

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **0**
Actual sample size reached: **48**
More than 1 sample in each individual
Actual sample size in each individual: **0**

Randomization (investigator's opinion)
Randomized

Randomization description
The research samples are divided into three groups using random allocation method and random numbers will be used for random allocation of the groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The level of anxiety of the patients at 21 o'clock, one night before surgery will be assessed by the researcher's assistance (researcher's assistance will be unaware to the intervention and control groups) for pretest and one hour before the operation begins Surgery for the post-test will be measured with the Spielberg tool.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2017-07-24, 1396/05/02

Ethics committee reference number

ir.medsab.rec.1396.42

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Mental and behavioural disorders

Primary outcomes

1

Description

Anxiety of patients before orthopedic surgery

Timepoint

At 21 o'clock, one night before surgery and one hour before the surgery begins

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The night before the surgery, the patients in the Cardamom Extract group will receive 10 drops (equivalent to 250 mg) of Cardamom Extract, dissolved in 50 cc of urban water.

Category

Treatment - Drugs

2**Description**

The diazepam group also will receive 5 mg oral diazepam tablets plus 50 cc of urban water.

Category

Treatment - Drugs

3**Description**

and the control group will receive only 50 cc of urban water.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Ali Hospital in Bojnourd

Full name of responsible person

Doctor Javad Shahinfar

Street address

Imam Ali Hospital, Payam Noor University Street,
Chamran street

City

Bojnourd

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3229 6764

Email

sahba.d59@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Docto Fereshteh Ghorat

Street address

Collegiate Paradise, Sabzevar Medical Sciences,
Sabzevar, Khorasan Razavi

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 8303

Email

shomia@ymail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Sadigheh Khalili Shomia

Position

Master of Science in Nursing, Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Collegiate Paradise, Sabzevar University of Medical
Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 8328

Fax**Email**

shomia@ymail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Sadigheh Khalili Shomia

Position

Master of nursing

Latest degree

Master

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Street address

Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 8328

Fax**Email**

shomia@ymail.com

Web page address

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 8328

Fax**Email**

shomia@ymail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Sadigheh Khalili Shomia

Position

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Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

City**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