Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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

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 updating data

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

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