

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effects of Passion Flower and placebo on reducing anxiety before the orthopedic surgeries

Protocol summary

Summary

This study is designed and implemented to compare the effects of Passion Flower with placebo on the anxiety before the orthopedic surgery in hospitalized patients of Ayatollah Kashani .In this double-blind clinical trial, 60 patients undergoing orthopedic surgery , age ranges between 50 to 25 years old referring to Ayatollah Kashani hospital, are going to be selected and randomly divided into two groups of case and control,30 in each group .The night before the action the case group is going to receive oral drops of Passion Flower and the control group receive placebo . Day of action on the basis of the Spielberger Trait anxiety questionnaire the level of latent anxiety (trait anxiety) and open (state anxiety) were recorded, as well as demographic information is also collected through questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512136480N11**

Registration date: **2016-01-22, 1394/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Mohammad Taghi Moradi

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 38 1334 9509

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Shahrekord University of Medical Sciences

Expected recruitment start date

2015-12-16, 1394/09/25

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Passion Flower and placebo on reducing anxiety before the orthopedic surgeries

Public title

Passion Flower effect on reducing anxiety before surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 25 to 50 years, not using psychotropic drugs and filling the informed consent form to participate in the study. Exclusion criteria: allergy to medicinal plants, the use of anesthesia alternative medicines in patients with a history of to mental illness, a history of previous surgery and pregnant women.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Shahrekord , Medical Sciences University Of

Street address

Kashani Blvd, Medical Sciences University Of

City

Shahrekord

Postal code

Approval date

2014-09-26, 1393/07/04

Ethics committee reference number

93-7-8

Health conditions studied

1

Description of health condition studied

Anxiety before the surgery

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

Primary outcomes

1

Description

The level of anxiety

Timepoint

Before the surgery

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before and 12 hours after the intervention

Method of measurement

Using barometer

2

Description

pulse

Timepoint

Before and 12 hours after the intervention

Method of measurement

Monitoring device

Intervention groups

1

Description

12 hours before surgery, 10 drops of vegetable oil of Passion Flower as a single dose is given to intervention group .

Category

Treatment - Drugs

2

Description

Control group is given 10 drops of placebo 12 hours before the intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic department, Ayatollah Kahani Hospital of Shahrekord

Full name of responsible person

Doctor Morteza Dehghan

Street address

Orthopedic department, Ayatollah Kashani Hospital, Shariati Boulevard

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University Of Medical Sciences

Full name of responsible person

Dr Kamal Solati

Street address

Kashani Boulevard, Vice Chancellery for Research and Technology, Shahrekord , Medical Sciences University Of

City

Shahrekord

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

Yes

Title of funding source

Shahrekord 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**

Ayatollah Kashani hospital

Full name of responsible person

Dr Morteza Dehghan

Position

Orthopedist

Other areas of specialty/work**Street address**

Orthopedics department, Ayatollah Kashani hospital, Parastar street

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

Ayatollah Kashani hospital

Full name of responsible person

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Position

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Ayatollah Kashani hospital

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Position

ph.D

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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*