

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Melissa officinalis extract on the anxiety of patients undergoing orthopedic surgeries

Protocol summary

Study aim

Determine the effect of Melissa officinalis extract on the anxiety of patients undergoing orthopedic surgeries in Bahonar hospital affiliated to Kerman University of Medical Sciences, 2018.

Design

Randomized clinical trial, triple blinded with parallel group design. Randomization will be done with minimization method.

Settings and conduct

In this clinical trial, the research population are patients candidate for orthopedic surgery admitted to Bahonar Hospital. The sample size is 40 people in each group. Sampling method is convenience and allocation of samples is done by Minimization method based on anxiety and gender variables. Patients in the intervention group receive 500 mg capsules containing Melissa officinalis extract at 4 and 10 pm before the surgery, and placebo (500mg capsules containing starch) is used in the control group. Before intervention and at 8 am on the operation day, the anxiety of patients in both groups is measured using the Spilberger Situation Questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being candidate for orthopedic surgery, being at the age of 18-60 years old, willing to participate in the study. Exclusion criteria: Previous history of orthopedic surgeries and diseases such as asthma, glaucoma, thyroid disorders, psychiatric disorders, pregnancy and lactation.

Intervention groups

Intervention group receives a 500 mg capsule containing the Melissa officinalis extract. Control group receives a 500 mg capsule containing the starch as a placebo

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N4**

Registration date: **2018-08-05, 1397/05/14**

Registration timing: **prospective**

Last update: **2018-08-05, 1397/05/14**

Update count: **0**

Registration date

2018-08-05, 1397/05/14

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Melissa officinalis extract on the anxiety of patients undergoing orthopedic surgeries

Public title

effect of Melissa officinalis on the anxiety

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate for orthopedic surgery Not being emergency patient Consent for participate in study Between 18-60 years old

Exclusion criteria:

Previous history of orthopedic surgery Use of Melissa officinalis regularly Pregnancy Lactation Glaucoma Hypothyroidism or Hyperthyroidism Asthma Suffering from psychosis Sensitivity to salicylates (ASA) Using antianxiety or tranquilizing drugs ten day before surgery Alcoholism

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random stratifying using minimization

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind patients, the pharmacist is asked to identify the drug and the placebo with numbers one and two so that the researcher does not know about the content of the capsules (drug or placebo). Patients are also given the capsules numbered 1 and 2 and the patient also doesn't know about the content of the capsules. The blinding will also be available for the analyzer, and after completing the analysis, the pharmacist will be asked to disclose the content of the capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committe of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-05-26, 1397/03/05

Ethics committee reference number

IR.RUMS.REC.1397.055

Health conditions studied**1****Description of health condition studied**

Surgery anxiety

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety score from Spielberger situation questionnaire

Timepoint

Pre intervention and post intervention on surgery day at 8.a.m

Method of measurement

Spielberger situation anxiety questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in the intervention group receive 500 mg capsules containing Melissa officinalis extract at 4 and 10 pm before the surgery

Category

Treatment - Drugs

2**Description**

Control group: his group receives a 500 mg capsule containing starch as a placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Hospital

Full name of responsible person

Motahareh Bagheri

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Gharani Street

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7613747181

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+98 34 3223 5011

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tabandeh Sadeghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

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