

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Consideration of the efficacy of lemon balm in decreasing anxiety of the patients before general surgery :a randomized double blind clinical trial

Protocol summary

Study aim

Evaluation of lemon balm on anxiety prior general operation a double blind clinical trial

Design

In this research , after preparation of plant and standardization base on cognition of essential oil constituent, drugs prepare from plant leaves powder as capsule 500 mg and placebo constituent starch . this clinical trial is conducted on 70 patients who refer to Tehran Shariati Hospital for general surgery with ASA (1or2 situation under general anesthesia after fill agreement form and divided based on inclusion and exclusion criteria in two groups.One day before surgery , patients anxiety degree are measured with STAI(state-trait anxiety Inventory).patients in both groups will be received one cap each 6 hours(total 4 cap) one day before surgery, at surgery day ,after patient arrive recovery . patients anxiety will be measured with Visual Analogue Scale.

Settings and conduct

70 patients who refer to Shariati hospital and underwent anesthesia , divided into two groups, drug and placebo and this study is double blinded

Participants/Inclusion and exclusion criteria

Patients refer for general surgery under anesthesia with ASA 1 or 2 situation .patients with heart valve disease ,kidney or hepatic disease ,psychological disturbance back ground ,uncontrolled blood pressure , who with tongue or communication disturbance,thyroid disturbance , pregnancy and lactation dont entered to research

Intervention groups

The drug group, where patients receive Lemon balm capsules, and the placebo group where patients receive placebo capsules.

Main outcome variables

Relaxation prior surgery , decrease anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141108019860N5**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

Arman Zargaran

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

zargarana@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Consideration of the efficacy of lemon balm in decreasing anxiety of the patients before general surgery :a randomized double blind clinical trial

Public title

Consideration of the efficacy of lemon balm in decreasing anxiety of the patients before general surgery :a randomized double blind clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

patients who candidate for general surgery refer to shariyati hospital with - ASA (1 or 2) situation that operate through general anesthesia

Exclusion criteria:

Patients with congestive heart failure Heart valve disease Hepatic or kidney disease Psychiatric disturbance back ground Uncontrolled blood pressure Patient with tongue and communication disturbance Pregnancy or lactation Thyroid function disturbance When intubation time is over than 10 second or larangoscopic grade is over than or equal to 3

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients divided into two groups with Block randomization (2:2)

Blinding (investigator's opinion)

Triple blinded

Blinding description

The people who are blinded are participants, principle investigator particularly in investigator initiated trials, healthcare providers (Physicians, nurses, physiotherapists, etc.) who care for participants during the trial, data collectors, outcome assessors. Drugs and placebos are prepared and labeled by pharmacists and others do not know which ones are drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

School of Persian Medicine, No. 27, Sarparast street, Tehran

City

Tehran

Province

Tehran

Postal code

1416663361

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3806

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

anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Patient's anxiety

Timepoint

When patient go to recovery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

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

Intervention group: lemon balm powder capsule receiver

Category

Treatment - Drugs

2

Description

Control group: placebo receiver

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Arman Zargaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

6th floor, Deputy of Research and Technology, Tehran University of Medical Sciences, Ghods Street, Keshavarz Street

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Arman Zargaran

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

No special conditions

From where data/document is obtainable

Contact to correspondence, Dr Arman Zargaran, by Email
azargaran@sina.tums.ac.ir

What processes are involved for a request to access data/document

sending request by email

Comments