Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 enterd 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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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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School of Persian Medicine, Tehran University of Medical Sciences, No. 27, Sarparast street
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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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azargaran@sina.tums.ac.ir
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