Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of bergamot essential oil aromatherapy on anxiety, salivary cortisol and alpha-amylase levels in patients undergoing laparoscopic cholecystectomy surgery

Protocol summary

Study aim
Determination of the effect of aromatherapy with bergamot essential oil on anxiety levels, salivary cortisol and alpha-amylase before laparoscopic cholecystectomy in patients referred to Imam Reza Hospital in Mashhad

Design
Clinical trial with control group, parallel groups, randomized, double blinded

Settings and conduct
In this clinical trial, 60 patients undergoing laparoscopic cholecystectomy, admitted to Imam Reza Hospital, will be selected randomly and assigned to either control or experimental groups randomly. Before the intervention, the Spielberger state anxiety questionnaire will be completed by the patients and the saliva samples will be collected. In the experimental group, two drops of 3% bergamot essential oil, which poured on a cotton ball, will be inhaled for 20 minutes. In the control group, two drops of odorless grape seed oil will be used, then saliva samples will be collected immediately after intervention and the Spielberger state anxiety questionnaire will be completed again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients undergoing laparoscopic cholecystectomy surgery aged 18 years and older 2. Can understand and speak Persian language 3. Interested in participating in the study Exclusion criteria: 1. Consumption of anti-anxiety drugs, antidepressants, narcotics, contraceptives, corticosteroids and other drugs affecting the autonomic nervous system and endocrine system 2. Addiction to alcohol and drugs (such as opium, hashish, glass, etc.) 3. Having surgery history

Intervention groups
In the experimental group, two drops of 3% bergamot essential oil will be poured onto a cotton ball and attached to the collar of the patient and we will be asked the patient to breathe normally for 20 minutes. In the control group, two drops of odorless grape seed oil will be used.

Main outcome variables
Anxiety, salivary cortisol, salivary alpha-amylase

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171113037428N2**
Registration date: **2018-03-25, 1397/01/05**
Registration timing: **prospective**

Last update: **2019-04-19, 1398/01/30**
Update count: **1**

Registration date
2018-03-25, 1397/01/05

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 935 147 3005

Email address
stud0670196835@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of bergamot essential oil aromatherapy on anxiety, salivary cortisol and alpha-amylase levels in patients undergoing laparoscopic cholecystectomy surgery

Public title
Effects of bergamot essential oil aromatherapy on anxiety, salivary cortisol and alpha-amylase levels in patients undergoing laparoscopic cholecystectomy surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing laparoscopic cholecystectomy surgery aged 18 years and older Can understand and speak Persian language Interested in participating in the study
Exclusion criteria:
Having any respiratory and allergic problems, such as asthma, systemic diseases, including metabolic and endocrine diseases such as diabetes, chronic liver and kidney disease, vision, hearing and smell problems, mental illness history confirmed by a psychologist , History of allergy to herbs, oral problems such as dry mouth and parotiditis Addiction to alcohol and drugs (such as opium, hashish, methamphetamine, etc.) Having surgery history Consumption of anti-anxiety drugs, antidepressants, narcotics, contraceptives, corticosteroids and other drugs affecting the autonomic nervous system and endocrine system
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The simple random sampling would be used to recruitment of the participants. In order to this, every day, each one of the subjects who would be on the list of operation room would be randomly assigned a code. Then, 50% of the patients would randomly assigned to the study through table of random numbers. After that, allocation of the participants to the intervention or control groups would be done based on weeks. In doing so, the weeks would randomly assigned to two blocks (A and B). Then, six blocks with block size of four would set via the block randomization software. Each block would be placed in an envelope and each week, one of the envelopes would opened, respectively. After that, the participants who recruited through table of random numbers would be assigned to the selected blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
The method of blindness is that the person who collects the questionnaires, the people who collect the laboratory tests from the patients, the people who report the laboratory tests, the statistician that performs data analysis are unaware of the treatment each patient receives.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz
City
shiraz
Province
Fars
Postal code
71345-1978
Approval date
2017-11-13, 1396/08/22
Ethics committee reference number
IR.SUMS.REC.1396.131

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F40
ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Anxiety
Timepoint
Before and immediately after the intervention
Method of measurement
Spielberger Anxiety questionnaire

Secondary outcomes

1

Description
Salivary cortisol
Timepoint
Before and immediately after the intervention
Method of measurement
Sampling of saliva

2

Description
Salivary Alpha-amylase
Timepoint
Before and immediately after the intervention
Method of measurement
Sampling of saliva

Intervention groups

1

Description
Intervention group: Aromatherapy with bergamot essential oil
Category
Other

2

Description
Control group: use of odorless grape seed oil
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital of Mashhad
Full name of responsible person
Fatemeh Araghi
Street address
Shiraz University of Medical Sciences, Zand Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3235 7282
Fax
+98 71 3230 7594
Email
araghif_69@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Sayed Bassir Hashemi
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3235 7282
Email
araghif_69@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Araghi
Position
postgraduate student of surgical technology
Latest degree
Bachelor
Other areas of specialty/work

Nursery
Street address
Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3235 7282
Email
araghif_69@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Niloufar pasyar
Position
Ph.D. in Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shiraz - Namazi Square - School of Nursing and Midwifery (SA)
City
Shiraz
Province
Fars
Postal code
0098-713451359
Phone
+98 71 3647 4254
Email
npasyar@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Araghi
Position
postgraduate student of surgical technology
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3235 7282
Email
araghif_69@yahoo.com

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