Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of aromatherapy with the essential oil of citrus aurantium on anxiety, pain, blood pressure, heart rate, nausea & vomitting in patients subject to elective laparoscopic cholecystectomy

Protocol summary

Study aim
Determination of the effect of aromatherapy with the essential oil of citrus aurantium on anxiety, pain, blood pressure, nausea & vomitting in patients subject to elective laparoscopic cholecystectomy

Design
Patients were randomly divided into two groups of 40, intervention and control groups and were treated with essential oil of citrus aurantium in the intervention group and distilled water in control group from one hour before to 30 minutes after surgery. Finally, the results are compared in terms of anxiety, pain, blood pressure, heart rate, nausea and vomiting.

Settings and conduct
This study is performed on patients referred to Imam Reza Hospital of Kermanshah University of Medical Sciences. Blindness is performed for all patients and data collector and analyzer.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 15-80 years, elective laparoscopic cholecystectomy surgery Exclusion criteria: Allergy to medicinal herbs, pulmonary allergy, age less than 15 years and over 80 years

Intervention groups
The smell of essential oil of citrus aurantium

Main outcome variables
anxiety; pain; blood pressure;heart rate; nausea ; vomitting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190816044541N1**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **registered_while_recruiting**
Last update: **2019-09-13, 1398/06/22**
Update count: **0**

Registration date
2019-09-13, 1398/06/22

Registrant information

Name
Akram o sadat Ziaziabari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3427 6301

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-06, 1398/04/15

Expected recruitment end date
2020-01-05, 1398/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with the essential oil of citrus aurantium on anxiety, pain, blood pressure, heart rate, nausea & vomitting in patients subject to elective laparoscopic cholecystectomy

Public title
determination of the effect of aromatherapy with the essential oil of citrus aurantium on anxiety, pain, blood

pressure, heart rate, nausea & vomitting in patients subject to elective laparoscopic cholecystectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients age between 15-80 elective laparoscopic cholecystectomy surgery

Exclusion criteria:

Allergy to medicinal herbs Pulmonary allergy Age less than 15 years and more than 80 years

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table

Blinding (investigator's opinion)

Triple blinded

Blinding description

All blind people only know that Participants are divided into two groups but they do not know the intervention type of each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kermanshah University of Medical Sciences

Street address

kermanshah university of medical sciences, shahid beheshti Blvd

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.KUMS..REC.1398.318

Health conditions studied

1

Description of health condition studied

anxiety, pain, blood pressure,heart rate, nausea & vomitting in laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in Spiel Berger questionnaire

Timepoint

Hours before and 30 minutes after surgery

Method of measurement

Spiel Berger questionnaire

2

Description

Pain score based on visual analogue scale

Timepoint

Hours before and 30 minutes after surgery

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

Reduce pain

Timepoint

30 minutes after surgery

Method of measurement

visual analogue scale

2

Description

Reduce anxiety

Timepoint

30 minutes after surgery

Method of measurement

Spiel Berger questionnaire

Intervention groups

1

Description
Control group:The smell of distilled water
Category
Placebo

2

Description
Intervention group: The smell of essential oil of citrus aurantium
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
akram o sadat ziaziabari
Street address
Imam reza hospital, parastar Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
dr. farid najafi
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kermanshah university of medical sciences, shahid beheshti Blvd
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Phone
+98 83 3838 4185
Email
farid_n32@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
akram o sadat ziaziabari
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Title and more details about the data/document
results will be shared after the anonymity of patients.
When the data will become available and for how long
the open access period is 6 months after publication of the results.
To whom data/document is available
all people
Under which criteria data/document could be used
For use by other researchers with the permission of the supervisor and approval of the research assistant
From where data/document is obtainable
by email: akram.ziaziabari@kums.ac.ir
What processes are involved for a request to access data/document
After acquiring the above, requested items will be sent.
Comments