

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of aromatherapy with the essential oil of citrus aurantium on anxiety, pain, blood pressure, heart rate, nausea & vomiting 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 & vomiting 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 ; vomiting

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

akram.ziaziabari@kums.ac.ir

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 & vomiting 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 & vomiting 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 &
vomiting 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

City

kermanshah

Province

Kermanshah

Postal code

6742775333

Phone

+98 83 3427 6307

Email

akram.ziaziabari@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

dr. farid najafi

Street address

kermanshah university of medical sciences, shahid beheshti Blvd

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kermanshah

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Postal code

6715847141

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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

javad aminisaman

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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aminisamanj99@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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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.ziabiabari@kums.ac.ir

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

After acquiring the above, requested items will be sent.

Comments