

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of chamomile on nausea, vomiting and abdominal flatulence after laparoscopic cholecystectomy

Protocol summary

Study aim

Determining the effect of chamomile on nausea, vomiting and abdominal flatulence after laparoscopic cholecystectomy

Design

Clinical trial with two intervention and control groups, with parallel groups, three- blind sides, Randomized using a table of random numbers, on 64 patients

Settings and conduct

This research is a clinical trial that will be performed on 64 patients undergoing laparoscopic cholecystectomy in selected hospitals affiliated to Isfahan University of Medical Sciences. Chamomile drops are prescribed in the intervention group and distilled water in the control group is using a table of random numbers when the patient enters the operating room and is performed as a primed. Nausea, vomiting, and bloating are checked before and after surgery (before discharge) and 2 hours later in the surgical unit in both groups.

Participants/Inclusion and exclusion criteria

Having laparoscopic cholecystectomy surgery Awareness and lack of psychotic symptoms Age between 18 and 65 years Having a BMI between 18 and 28 Having a history of allergies to herbal medicine Being pregnant during the study Having known gastrointestinal diseases

Intervention groups

Chamomile drops in the intervention group and distilled water in the control group are prescribed , when the patient enters the operating room and is performed as a primed. Nausea, vomiting, and bloating are checked before and after surgery (before discharge) and 2 hours later in the surgical unit in both groups.

Main outcome variables

The use of chamomile medicine to provide evidence-based solutions related to nausea, vomiting, and abdominal bloating after surgery in patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200612047737N1**

Registration date: **2020-07-27, 1399/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-27, 1399/05/06**

Update count: **0**

Registration date

2020-07-27, 1399/05/06

Registrant information

Name

raziieh salimi zadak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4724 2804

Email address

salimi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-07, 1399/04/17

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chamomile on nausea, vomiting and abdominal flatulence after laparoscopic cholecystectomy

Public title

The effect of chamomile on nausea, vomiting and abdominal flatulence after laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having laparoscopic cholecystectomy surgery Awareness and lack of psychotic symptoms Age between 18 and 65 years Being NPO Having a BMI between 18 and 28

Exclusion criteria:

Having a history of allergies to herbal medicine Being pregnant during the study Having vestibular symptoms Having known gastrointestinal diseases

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Before sampling, using the table of random numbers, which will be given two numbers 1 and 2, and number 1 as the control group and number 2 as the intervention group, and the samples in the order of the numbers given by this software, they will be placed in groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

1- The type of substance and its effect are not described for patients (one blind sides). 2- The intervention will be performed by the researcher and all questionnaires will be completed by the researcher's colleague (two blind sides) 3- Data analyzer will not know the type of groups (three blind sides)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-03-08, 1398/12/18

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.745

Health conditions studied

1

Description of health condition studied

Nausea and vomiting, abdominal Flatulence

ICD-10 code

R11.2, R14

ICD-10 code description

Nausea with vomiting, unspecified, Flatulence and related conditions

Primary outcomes

1

Description

Nausea

Timepoint

Before surgery, after surgery in recovery, 2 hours in the ward

Method of measurement

Analog visual scale

2

Description

vomiting

Timepoint

Before surgery, after surgery in recovery, 2 hours in the ward

Method of measurement

View researcher and Ask the patient

3

Description

abdominal flatulence

Timepoint

Before surgery, after surgery in recovery, 2 hours in the ward

Method of measurement

Analog visual scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Chamomile drops produced by Tehran Zardband Pharmaceutical Company, containing the active ingredient Camazolen in the amount of 0.4%, in the amount of -20 15 drops, will be given to patients once and at the beginning of the patient's arrival in the operating room . The type of substance and its effect on patients are not described .Its effects will be measured after surgery in recovery and ward.

Category

Prevention

2

Description

Control group: Distilled water will be given to patients once as soon as the patient enters the operating room .The type of substance and its effect on patients are not described. Its effects will be measured in recovery and section after surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Amin, Kashani

Full name of responsible person

Razieh Salimi Zadak

Street address

Hezar jerib,Milad Dormitory

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8174673461

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Email

salimi.r7118@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Soheila Bakhtiari

Street address

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+98 31 3792 7584

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bakhtiari@nm.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Razieh Salimi Zadak

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Soheila Bakhtiari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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