Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

razieh 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
Isfehan
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Soheila Bakhtiari

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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
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Soheila Bakhtiari
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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