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 side).
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
City
Isfahan
Province
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Postal code
8174673461
Phone
+98 51 4724 2804
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
Hezar Jerib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 7584
Email
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
Street address
Hezar Jerib
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8174673461
Phone
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Email
salimi.r7118@gmail.com

Person responsible for scientific inquiries
Contact
Name of organization / entity
Person responsible for updating data

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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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