Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of two methods of family visits and acupressure on nausea and vomiting and some physiological indicators after laparoscopic cholecystectomy in the post-anesthesia care unit.

Protocol summary

Study aim

Comparison of the effect of two methods of family visits and acupressure on nausea and vomiting and physiological indicators of patients after laparoscopic cholecystectomy in the post-anesthesia care unit in Al-Zahra Hospital in Isfahan in 1999-98.

Design

Clinical trial with control group, with parallel, single blind groups, randomized to 105 patients. The website (sealedenvelope.com) was used to randomize.

Settings and conduct

This study is performed in the elective operating room of Al-Zahra Hospital in Isfahan.For the first group, acupressure is applied in two points by the researcher . In the second group, a family member comes to the patient's bedside in the recovery unit and calms the patient by touching and talking. In the third group, no intervention is applied by the researcher and the care is routinely performed. In order to perform blinding in this study, information is collected by a research colleague, and blindness is also performed in data analysis.

Participants/Inclusion and exclusion criteria

Patients who are candidates for elective laparoscopic cholecystectomy, Conscious patients, aged 65-18, with no history of mental, cardiovascular, hypertension, or gastrointestinal illnesses who do not experience nausea or vomiting before surgery.

Intervention groups

In the acupressure group, pressure will be applied on each of the P6 and LI4 points with the thumb for 2 to 5 minutes, 10 seconds of pressure is applied and 2 seconds of rest is given to the extent that the person in that point Feeling a slight pain, tingling and numbness. In the group with family visitation, the visitor should be present for 7 to 10 minutes on the patient's bedside, touching the patient's head, face, and hands, and comforting him or her by saying kind words. In the control group, routine care of the recovery department is performed.

Main outcome variables

Physiological indicators; nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047017N1**
Registration date: **2020-07-19, 1399/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-19, 1399/04/29**
Update count: **0**

Registration date

2020-07-19, 1399/04/29

Registrant information

Name

Fateme Zeraatpishe

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4333 6306

Email address

zeraatpishe@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-06, 1399/03/17

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two methods of family visits and acupressure on nausea and vomiting and some physiological indicators after laparoscopic cholecystectomy in the post-anesthesia care unit.

Public title

Comparison of the effect of two methods of family visits and acupressure on nausea and vomiting and some physiological indicators after laparoscopic cholecystectomy in the post-anesthesia care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for laparoscopic cholecystectomy Patients who are alert and aware of time and place Patients with age 18-65

Exclusion criteria:

Patients who are candidate for emergency cholecystectomy laparoscopic Patients with a history of mental illness Patients with a specific digestive problem that leads to nausea and vomiting Patients with cardiovascular disease and hyperytension

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to create a balance in the number of samples allocated to each of the studied group, block randomization method will be used and the size of each block will be 3. A reputable website (https://www.sealedenvelope.com/simple-randomiser/v1/lists) is used to randomly assign random blocks, then the samples are placed in each of the intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to perform blindness in this study, information will be collected by a research colleague who, to ensure the correct performance of the colleague, the information for 5 patients is randomly recorded by the researcher and research colleague and then compared with each other. Blindness will also be considered for data analysis.

Placebo

Not 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

Isfahan-Hezar Jerib St.-Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.027

Health conditions studied

1

Description of health condition studied

cholecystitis

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

2

Description of health condition studied

postoperative nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Average of blood pressure

Timepoint

Before induction of anesthesia, after the intervention, up to 12 hours in the surgical unit

Method of measurement
Monitoring system

2

Description
Average oxygen saturation of arterial blood
Timepoint
Before induction of anesthesia, after the intervention, up to 12 hours in the surgical unit
Method of measurement
pulse oximeter probe

3

Description
The average number of heartbeats
Timepoint
Before induction of anesthesia, after the intervention, up to 12 hours in the surgical unit
Method of measurement
Monitoring system

4

Description
The average number of breaths
Timepoint
Before induction of anesthesia, after the intervention, up to 12 hours in the surgical unit
Method of measurement
Monitoring system

5

Description
Average of patients pain intensity
Timepoint
Before and after the intervention
Method of measurement
Visual Analogue Scale

6

Description
The average of vomiting number, severity and extent
Timepoint
Before induction of anesthesia, before leaving recovery, up to 12 hours in the surgical unit
Method of measurement
Rhodes questionnaire

7

Description
The average score of the number, duration and severity of nausea
Timepoint
Before induction of anesthesia, before leaving recovery, up to 12 hours in the surgical unit
Method of measurement
Rhodes questionnaire and Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1, which visits the family, explains to the patient that after surgery and in recovery, a first-degree relative will be present at his or her bedside and asked to express the name of a person who feels most comfortable with him or her . The visitor is then assessed separately and their abilities to participate in the study are assessed. People under the age of 18 and those who are scared and anxious when they see monitors and equipment next to the patient are not suitable to participate in the study. After confirming the accompanying ability to participate in the study, the etiquette of meeting in recovery is explained to them. If the researcher finds that the patient does not understand the explanation with the questions and answers while teaching, the sample will be removed from the study. This training will be face-to-face and will be done by the researcher and the companion will be asked to control their nerves, give all their focus to their patient, face the patient with a determined spirit, Touch his head, face or hands and comfort him. Then, visitor enters recovery after put on the surgical gown and shoes and washing his hands. In order to protect the privacy of other patients, partitions around the sample's bed will be placed. The visitor will stay with the patient for 7 to 10 minutes with the permission of the person in charge of the recovery department. This intervention will be done in addition to routine recovery care, including warming the patient, oxygen therapy, fluid therapy, pain relief, vital signs check, surgical wound and drainage control, and controlling nausea and vomiting, and more. In the case of severe nausea and vomiting, patients will take medications(Ondansetron) , according to doctor's diagnosis.
Category
Other

2

Description
For the intervention group 2, which is acupressure, the researcher will be trained before the intervention under the supervision of a specialist in acupressure. Pressure will be applied to each of the P6 and LI4 points with the thumb for 2 to 5 minutes to apply pressure, so that pressure is applied for 10 seconds and stopped for 2 seconds. The intensity of the pressure would be such that one third of the thumbnails turn white and the pressure is applied rotational in a clockwise direction. The intensity of the pressure should be optimal, firm and stable, and pleasant to the point of pain. It should be high enough for the person to feel mild pain, tingling, and numbness at that point. at first the pressure apply in point P6 and then LI4 to the left hand. This intervention will be done in addition to routine recovery care. In the

case of severe nausea and vomiting, patients will take medications(Ondansetron), according to doctor's diagnosis.

Category

Other

3

Description

In group 3, which is the control group, routine recovery proceedings include warming the patient, oxygen therapy, fluid therapy, pain relief, vital signs check, surgical wound and drainage control, will be done, And no intervention is done by the researcher. And to control nausea and vomiting, if patients in any of the three groups suffers from severe nausea and vomiting, medication (Ondansetron) will be taken by patients, according to doctor's diagnosis.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Akram Aarabi

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Isfahan, Hezar-Jerib St, Isfahan University of Medical Sience

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Akram Aarabi

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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
Fateme Zeraatpishe

Position
MSc Student

Latest degree
Master

Other areas of specialty/work
Surgical Technology (opeerating room)

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Akram Aarabi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fateme Zeraatpishe
Position
MSc Student
Latest degree
Master
Other areas of specialty/work
Surgical Technology (operating room)
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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