

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of jacobson relaxation method and Hugo point massage on Vital sign and severity of pain in patients with cholecystectomy

#### Protocol summary

##### Summary

Aims: The purpose of this study is to evaluate and compare the impact of the Hugo point massage and Jakobson relaxation method on vital signs and pain in patients with cholecystectomy and determine the most effective method to reduce pain and improve patients' vital signs of patients for application to bedside nurses in surgery. Study design: this is a clinical trial study and population of study is 75 who underwent laparoscopic cholecystectomy were randomly divided into three groups and Hugo point massage, relaxation would be allocated Jacobson and controls (n = 25 per group). Inclusion criteria: health in the hands, particularly between the fingers, sixty, having higher average pain intensity and rate (intensity of pain 3 or later), the lack of addiction to drugs, a sedative, alcohol and. . . The lack of sensory disorders . Exit criteria: incidence of severe complications after surgery during hospitalization, such as severe bleeding, edema, acute infections, drugs, tranquilizers, alcohol, diabetics. How to do: according to the standard protocols interventions during the three days when the pain is more than 3 on a numeric scale will be done in two groups. Vital signs (systolic and diastolic blood pressure, pulse, respiratory rate) and the pain will be measured before and after each intervention. In the control group baseline and after three days of operation will be measured vital signs and pain. Finally, the results will be compared among the three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021126522N1**

Registration date: **2016-05-15, 1395/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-15, 1395/02/26

##### Registrant information

###### Name

MohamadTaher Rezanejad

###### Name of organization / entity

Yasuj University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor of Research of Yasuj University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-04-20, 1395/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of jacobson relaxation method and Hugo point massage on Vital sign and severity of pain in patients with cholecystectomy

##### Public title

Jacobson relaxation and Hugo point massage impact on vital signs and pain

##### Purpose

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: is laparoscopic surgery, organ health of the hands, especially the thumb, having a higher average pain severity (based on a numeric scale of pain intensity 3 and up), do not member of Health care providers, gaining full consciousness after the surgery, not addicted to narcotics, sedatives, alcohol, etc., lack of sensory and motor disorders, lack of hearing impairment, lack of any other physical and mental disorders from recent surgery, no history of use Hugo point massage and relaxation Jacobson, lack of chronic pain in other parts of the body, such as migraine, low back pain and so on. Exclusion criteria: severe post-operative complications during hospitalization, such as severe bleeding, edema, acute infections, need more care and transferred to the intensive care unit after surgery, use illegal drugs (except substances that are part of the routine management patient (eg, petedine)), sedatives, alcohol, diabetes, patient dissatisfaction and lack of access to appropriate conditions to continue research ..

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 75

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Yasuj University of Medical Sciences

##### **Street address**

Ethics Committee, Deputy of Research and Technology, Yasuj University of Medical Sciences, Jhad Square

##### **City**

Yasuj

##### **Postal code**

### **Approval date**

2016-02-08, 1394/11/19

### **Ethics committee reference number**

ir.yums.REC.1394.143

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Cholecystectomy

#### **ICD-10 code**

K81.0

#### **ICD-10 code description**

Acute cholecystitis

## **Primary outcomes**

### **1**

#### **Description**

Pain and vital signs

#### **Timepoint**

3 days

#### **Method of measurement**

Numerical Scale of pain (NRS) and the vital sign form

## **Secondary outcomes**

### **1**

#### **Description**

Reducing pain and improving vital signs

#### **Timepoint**

3 days

#### **Method of measurement**

The numeric scale of pain and vital sign form

## **Intervention groups**

### **1**

#### **Description**

The samples Based on a random table, randomly assigned to experimental groups Hugo point massage, relaxation Jacobson and will be the control group. The number of samples for each group, 25 patients and in total, 75 people will be studied. For each of them about how to do research, and the aim of study, then Informed consent of the patient Will be taken and Will ensure .that the above-mentioned method, there is no harm and Will not disruptions in the process of his care. In this study use demographic questionnaire and standardized numerical pain scale (10-0) for collect information. To check vital signs, the patient's vital signs before and after intervention data will be checked and entry to form. Therefore, the normal respiratory rate of 12 to 20, less than 12 Bradypnea and over 20 will be considered tachypnea. Use phygmomanometer to measure blood pressure of patients. if systolic pressure ranging from 140 to 110 mm Hg and diastolic blood pressure 90-80

mm Hg is considered normal. Palpating the patient's pulse rate with the help of over a minute to be counted and considered normal in the 60-100 range and fewer than 60 bradycardia and tachycardia in the top 100 will be considered. The intervention will continue for three days. And until the patients in the hospital and after discharge interventions in the hospital until three days interventions will be done in the home environment. Protocol Hugo point massage: massage of the people will be asked to put in the required position. So researchers will be facing. when the pain on the patient more than 3 score on a numerical pain scale a researcher put his his thumb on right hand of patient and use small bag of ice for pressure on the patient's right hand (hugo point). To prevent discomfort, pressure for deep and back - strength beyond that point forward Hugo and as far as change in nail color will be applied researcher. This procedure repeat three times, so repeated then people explain their pain on a numerical rating scale to determine pain. To search for Suitable of time and its effectiveness of procedure will asked DeQi emotions collection including feeling of heat, numbness, numbness, pain, heaviness and relaxation. Jacobson relaxation protocol: in this group relaxation techniques Jacobson (progressive muscle relaxation and deep breathing) will be used. 6 relaxation sessions over the three days, each session for 30 minutes for patients in the experimental group will be done. the data from the forms and numerical pain scale observation and examination, will be extracted. Educational program in the first session, including progressive relaxation technique for practical steps will be. The relaxation will be monitored by patients. Patients will be asked every single muscle in relaxation of the muscles of the foot and facial muscles, including 16muscles, the first contract and then relax. Patients his muscles twitched and then counted by counting the number 5 to number 10 will loose. The same steps as for the feet and legs, thighs, abdomen, chest, buttocks, hands and forearms, arms, shoulders, neck, forehead, tongue and jaw, eyes and face will repeat until you feel Shell has integrated their entire body. During the relaxation time patients will take a deep breath. Selection mode to relaxation mode is lying. In subsequent meetings and relaxation process will be explained to the patient by the investigator and the patient's description of relaxation researcher to researcher will run under. Control: There will be no intervention in the control group. Patients in the usual care group received and it will be completed only by means of research. The amount and type of housing by patients before and during the intervention will be compared with each other in the checklist.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

shahid beheshti hospital of yasuj city

**Full name of responsible person**

**Street address**

**City**

yasuj

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Deputy of Research and Technology of yasuj University of medical science.

**Full name of responsible person**

shahla najafi

**Street address**

Yasuj- Street of shahid Galilee - School of Nursing and Midwifery

**City**

yasuj

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Deputy of Research and Technology of yasuj University of medical science.

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

School of Nursing and Midwifery of Yasouj

**Full name of responsible person**

shahla najafi

**Position**

coach

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*