Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compare the Effect of Acupressure and Auriculotherapy on Shoulder Pain in Patients subjected to Laparoscopic Cholecystectomy

Protocol summary

Study aim
Determining the Comparison the Effect of Acupressure and Auriculotherapy on Shoulder Pain in Patients subjected to Laparoscopic Cholecystectomy

Design
Clinical trial with control group, single blind on 93 patients. The permutation Blocking Method will be used for Randomization.

Settings and conduct
Patients undergoing Cholecystectomy in Birjand hospitals are divided into three groups: Acupressure, Auriculotherapy and Control. After surgery, the amount of pain is measured with the VAS (Visual Analogue Scale) scale, then the intervention is performed. Patients will complete the VAS scale again 1 hour, 4 hours and 8 hours after the intervention. The researcher assistance who is unaware of the groupings and type of interventions in each group is used for blinding.

Participants/Inclusion and exclusion criteria
Entry conditions: patients stay in the hospital for at least one day after surgery; be able to provide informed written consent; no lesions or wounds in the areas where acupressure is to be applied; no history of chronic pain in the shoulder or neck; no need for simultaneous combination surgery. Exit conditions: existence of any disease related to bleeding or abnormal blood clotting; pregnancy or breastfeeding; history of seizures, dementia.

Intervention groups
After surgery, the amount of pain is measured with the VAS (Visual Analogue Scale) scale, then the intervention is performed. Acupressure is performed on the GB21, ST38, TW15 points by the researcher's thumb pulp. Auriculotherapy is performed on the shoulder, shoulder joint, and clavicle with ear probe. The control group will not receive any intervention. All three groups will receive routine care. Patients will complete the VAS scale again 1 hour, 4 hours and 8 hours after the intervention.

Main outcome variables
Shoulder Pain in Patients subjected to Laparoscopic Cholecystectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220310054249N1**
Registration date: **2022-03-25, 1401/01/05**
Registration timing: **prospective**

Last update: **2022-03-25, 1401/01/05**
Update count: **0**

Registration date
2022-03-25, 1401/01/05

Registrant information

Name
Mona Zohourparvaz

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3621 8648

Email address
monazparvaz@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Compare the Effect of Acupressure and Auriculotherapy on Shoulder Pain in Patients subjected to Laparoscopic Cholecystectomy

Public title
Acupressure in Cholecystectomy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients stay in the hospital for at least one day after surgery Be able to provide informed written consent No lesions or wounds in the areas where acupressure is to be applied Have no history of chronic pain in the shoulder or neck No need for simultaneous combination surgery

Exclusion criteria:
Existence of any disease related to bleeding or abnormal blood clotting Pregnancy or breastfeeding History of seizures Dementia

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **93**

Randomization (investigator's opinion)
Randomized

Randomization description
All sample subjects are divided into three equal groups by simple random methods. First, 93 cards (equal to the number of sample volumes) will be prepared. Then A, B or C will be written on each card (31 cards A, 31 cards B and 31 cards C). These cards will be placed inside a box so that no one can see the cards inside the box. After shuffling the cards by the researcher, patients are asked to randomly take a card from the box (selected cards will not be returned to the box after selection). Thus, people are divided into three groups of 31 people A, B and C. In this way, three cards are prepared and one of the numbers one (acupressure), 2 (auriculotherapy) and 3 (control) will be written on each card. These cards are placed in a box and after shuffling, the researcher will randomly select a card for each group (the selected cards will not be returned to the box after selection).

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the researcher assistance will be used to complete all questionnaires to blind and prevent bias in the results. This person will be unaware of the groupings and the type of interventions that are performed in each group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences

Street address
Ghaffari St., Birjand University of Medical Sciences, Vice Chancellor for Research and Technology

City
Birjand

Province
South Khorasan

Postal code
9717853577

Approval date
2022-03-09, 1400/12/18

Ethics committee reference number
IR.BUMS.REC.1400.444

Health conditions studied

1

Description of health condition studied
Cholecystitis

ICD-10 code
K81

ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
Shoulder Pain after Laparoscopic Cholecystectomy

Timepoint
Pain is measured after surgery and immediately after entering the ward, 1 hour, 4 hours and 8 hours after the intervention.

Method of measurement
VAS Scale (Visual Analog Scale)

Secondary outcomes

1

Description

Comfort

Timepoint

Comfort is measured after surgery and immediately after entering the ward, 1 hour, 4 hours and 8 hours after the intervention.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Acupressure is performed on GB21 points in the most prominent part of shoulder muscle, ST38 in lateral tibial cortex and between the distance between external ankle and popliteal crease, TW15 in the middle of the hypothetical line between the lower end of the seventh cervical vertebra and the acromion head by the researcher's thumb pulp. The amount of pressure is 3 to 4 kg, which is calibrated by the pressure of the therapist's hand on a digital scale. Pressure time for each point is 3 minutes of pressure and 1 minute of rest to our patient between two points on one side of the body (the same side that hurts).

Category

Rehabilitation

2

Description

Intervention group: Auriculotherapy is performed on the shoulder, shoulder joint, and clavicle points by a special ear prop. The amount of prop pressure in the ear is 1 to 2 kg, which is calibrated on a digital scale. Pressure time for each point is 3 minutes of pressure and 1 minute of rest to the patient between two points in one ear (ear is the same part of the body that is in pain).

Category

Rehabilitation

3

Description

Control group: The control group will not receive any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Department of Birjand Hospitals

Full name of responsible person

Dr. Mohammad Reza Ghasemian Moghaddam

Street address

Ayatollah Taleghani St., Imam Reza Hospital

City

Birjand

Province

South Khorasan

Postal code

9714811151

Phone

+98 56 3222 2300

Email

emamreza@bums.ac.ir

Web page address

https://www.bums.ac.ir/page-emamrezares

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Reza Miri

Street address

University of Medical Sciences - Education and Research Building - Second Floor - Vice Chancellor for Research and Technology

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1200

Email

Miri_moh2516@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mona Sadat Zohourparvaz

Position

Senior Nursing Student

Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Birjand University of Medical Sciences, Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1407
Email
monazparvaz@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Seyyed Abolfazl Vagharseyyedin
Position
Associate Professor of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Birjand University of Medical Sciences, Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1407
Email
Waghars@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mona Sadat Zohourparvaz
Position
Senior Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Birjand University of Medical Sciences, Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1407
Email
monazparvaz@gmail.com

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