Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of acupressure on pain and sleep quality of cancer patients undergoing surgery admitted to the intensive care unit

Protocol summary

Study aim
Determining the effect of acupressure on pain and sleep quality of cancer patients after surgery in the intensive care unit

Design
A clinical trial with a control group with parallel groups, single blind, on 80 patients who will be assigned to two groups of experimental and control by blocking method with size 4.

Settings and conduct
This study will be performed in the intensive care unit of the Cancer Institute of Imam Khomeini Hospital Complex and patients who meet the inclusion criteria will be included in the study. This is a single blind study so that patients, will be unaware of receiving original or similar acupressure.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at least 18 years old, being diagnosed with any type of cancer, pain related to cancer surgery and pain expressed by the patient, having full consciousness, ability to listen and speak, and having a minimum ability to read and write Exclusion criteria: cognitive and behavioral disorders (self-manifestation), mental disorder to the extent of daily use of psychiatric drugs, and history of amputation, surgery, or wound in pressure points

Intervention groups
Intervention group: On the second and third day after surgery, patients with cancer who suffers severe pain, are exposed to massage on the LI4 and SP6 points with 10 seconds of pressure, 2 seconds of rest for 8 minutes in the morning and evening. Control group: On the second and third day after surgery, patients with cancer who suffers severe pain are exposed to the superficial touch of LI4 and SP6 points for 10 seconds of pressure, 2 seconds of rest for 8 minutes in the morning and evening.

Main outcome variables
Pain and sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220111053686N1**
Registration date: **2022-05-29, 1401/03/08**
Registration timing: **prospective**

Last update: **2022-05-29, 1401/03/08**
Update count: **0**

Registration date
2022-05-29, 1401/03/08

Registrant information
Name
Mahya Jafari
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 7726 3242
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-31, 1401/03/10

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of acupressure on pain and sleep quality of cancer patients undergoing surgery admitted to the intensive care unit

Public title
The effect of acupressure on pain and sleep quality in cancer patients after surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Be at least 18 years old Diagnosis of any type of cancer Having chronic pain in connection with cancer surgery and its expression by the patient Having full consciousness Listening and speaking ability Minimum ability to read and write

Exclusion criteria:
cognitive and behavioral disorders mental disorder to the extent of daily use of psychiatric drugs history of limb amputation, surgery or wound in pressure points

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block randomization method will be used to allocate samples (block size: 4). Thus, the letter A is considered for the intervention group and the letter B for the control group. Then all the permutation combinations of the letters A, A, B and B, which are 6 different combinations, are written on the 6 cards in the following order:AABB،ABBA،ABAB،BAAB،BABA،BBAA.Then, from numbers 1 to 6, a card will be randomly selected by patient number one.For example, number 2 was chosen, which means that the first person in the intervention group, the next two people in the control group and the fourth person in the intervention group, and this process continued until the sample size reached the quorum.

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a single blind study in which patients are unaware that they are receiving acupressure or gentle surface pressure. The intervention group will receive acupressure and the control group will receive a gentle surface pressure at the same points.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Ethics Committee of Shahid Rajaei Cardiovascular Center

Street address
2nd floor, research building, Shahid Rajaei Research & Training Hospital, Next to Mellat Park, Vali-Asr Ave, Tehran, IRAN

City
tehran

Province
Tehran

Postal code
1995614331

Approval date
2022-03-12, 1400/12/21

Ethics committee reference number
IR.RHC.REC.1400.121

Health conditions studied

1

Description of health condition studied
other acute post procedural pain

ICD-10 code
G89.18

ICD-10 code description
Other acute post procedural pain

Primary outcomes

1

Description
Percentage of people with a pain score of 7 or more

Timepoint
Twice a day on the second and third days after surgery

Method of measurement
Visual Analogue Scale

2

Description
sleep quality

Timepoint
Before the intervention and in the morning after the last intervention

Method of measurement
The Richards-Campbell Sleep Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 40 patients with cancer admitted to the intensive care unit who suffer severe pain after surgery (pain score of 7 or more based on the Pain Visual Analog Scale), on the second and third day after surgery will be exposed to acupressure massage, on the LI4 points (between the base of thumb and index finger) and the SP6 points (the shin bone on the inside of the ankle) for periods of 10 seconds of pressure and 2 seconds of rest for 8 minutes in the morning and evening.

Category
Rehabilitation

2

Description
Control group: 40 cancer patients admitted to the intensive care unit who suffer severe pain after surgery (pain score of 7 or more based on the Pain Vision Analog Scale), on the second and third days after surgery will be exposed to superficial touch on LI4 points and SP6 during periods of 10 seconds of pressure and 2 seconds of rest for 8 minutes in the morning and evening.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Tehran

Full name of responsible person
Mahya Jafari

Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran

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Tehran

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Rajaei Cardiovascular Research and Training Center

Full name of responsible person
Dr Fidan Shabani

Street address
2nd floor, research building, Shahid Rajaei Research & Training Hospital, Next to Mellat Park, Vali-Asr Ave, Tehran, IRAN

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http://internatinal-unit.rhc.ac.ir/fa

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Rajaei Cardiovascular Research and Training Center

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
Iran University of Medical Sciences

Full name of responsible person
Mahya Jafari

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Unit 1, No. 12, Jahangiri Alley, Mahmoudi St, South Madani St

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahya Jafari

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on age, sex, type of cancer, marital status, occupation, education, place of residence, history of smoking, drug and alcohol use, and receiving painkillers on the second and third days after surgery can be shared.

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

All academics and researchers and professionals in the field of treatment

Under which criteria data/document could be used

.In order to conduct more and more comprehensive research and complete the research process for its clinical application..

From where data/document is obtainable

mahya jafari jafari.mh1990@gmail.com

What processes are involved for a request to access data/document

After sending an email to the researcher, the file and documents will be provided to the people in a short time.

Comments