

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

Phone

+98 21 7726 3242

Email address

m-jafari@alumnus.tums.ac.ir

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		Secondary Ids	empty
Public title	The effect of acupressure on pain and sleep quality in cancer patients after surgery	Ethics committees	
Purpose	Supportive	1	
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	Ethics committee	
Age	From 18 years old	Name of ethics committee	Medical Ethics Committee of Shahid Rajaei Cardiovascular Center
Gender	Both	Street address	2nd floor, research building, Shahid Rajaei Research & Training Hospital, Next to Mellat Park, Vali-Asr Ave, Tehran, IRAN
Phase	N/A	City	tehran
Groups that have been masked	- Participant - Data analyser	Province	Tehran
Sample size	Target sample size: 80	Postal code	1995614331
Randomization (investigator's opinion)	Randomized	Approval date	2022-03-12, 1400/12/21
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.	Ethics committee reference number	IR.RHC.REC.1400.121
Blinding (investigator's opinion)	Single blinded	Health conditions studied	
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.	1	
Placebo	Not used	Description of health condition studied	other acute post procedural pain
Assignment	Parallel	ICD-10 code	G89.18
Other design features		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 Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

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Phone

+98 21 6119 2511

Email

Imamhospital@tums.ac.ir

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

City

Tehran

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Tehran

Postal code

1995614331

Phone

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Fax

+98 21 2204 2026

Email

fidannahal@yahoo.com

Web page address

<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

Street address

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

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Person responsible for scientific inquiries

Contact

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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