Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of transcutaneous electrical nerve stimulation with acupressure on the fatigue of colorectal cancer patients Undergoing chemotherapy

Protocol summary

Study aim
Comparison of the effect of transcutaneous electrical nerve stimulation with acupressure on fatigue in colorectal cancer patients undergoing chemotherapy

Design
This is a two-group randomized controlled clinical trial with a pre-test/post-test design, parallel groups, randomized, ,conducted on 30 patients per group. Random allocation is performed using the Sealed Envelope website.

Settings and conduct
The oncology departments for women and men are located in Imam Reza Hospital, Ghaem Hospital, and Omid Hospital in Mashhad. Units are randomly assigned to one of two groups: TENS and acupressure.

Participants/Inclusion and exclusion criteria
Inclusion criteria include willingness to participate in the study, diagnosis of colorectal cancer ، hospitalization for chemotherapy for at least 48 hours, , undergoing FOLFOX chemotherapy regimen, absence of metastatic cancer (documented in medical records). Exclusion criteria include patient being in critical condition, low platelet count, decreased level of consciousness, use of other therapies, and having metastatic cancer.

Intervention groups
TENS group: The TENS intervention involves electrical stimulation of sensory nerves in the lower back and lower legs with a current intensity tolerable for the patient and a frequency of 100 Hz. This will be conducted in 4 sessions, lasting 30 to 45 minutes each, with 2 sessions on 2 consecutive days during one chemotherapy cycle and the subsequent 2 sessions during the following chemotherapy cycle, which occurs every other week. Acupressure group: The acupressure intervention involves applying pressure to points ST-36, LR-3, GB-20, and TW-5 to the point of discomfort for the patient, then reducing the pressure slightly for 2 to 5 minutes at each point, daily for 2 weeks (14 sessions) between two consecutive chemotherapy cycles occurring every other week.

Main outcome variables
Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250311065043N1**
Registration date: **2025-04-14, 1404/01/25**
Registration timing: **prospective**

Last update: **2025-04-14, 1404/01/25**
Update count: **0**

Registration date
2025-04-14, 1404/01/25

Registrant information

Name
Matin Abdollahi yousefabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5452 0144

Email address
matin09307@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-19, 1404/01/30

Expected recruitment end date
2025-07-21, 1404/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of transcutaneous electrical nerve stimulation with acupressure on the fatigue of colorectal cancer patients Undergoing chemotherapy

Public title
Comparing the Effects of Acupressure and TENS on Fatigue Improvement in Patients Undergoing Chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Undergoing chemotherapy for colorectal cancer. No metastatic cancer (documented in the record) Chemotherapy appointment requires at least 48 hours' notice. Attendance for chemotherapy to be performed in 2 consecutive cycles, back-to-back. Has not used other treatments such as cryotherapy, thermotherapy, and radiotherapy concurrently. No metallic objects in the body.
Exclusion criteria:
Having metastatic cancer History of hospitalization due to mental health issues Having platinum or a foreign metal object in the body Simultaneous use of therapeutic methods to improve fatigue Being hospitalized for just one course of chemotherapy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two groups using block randomization via the Sealed Envelope website, with mixed block sizes of 2 and 4. The groups are sequentially labeled A and B, where A represents the TENS group and B represents the Acupressure group (e.g., ABBABBA...). After allocation, the sequence is numbered, and the letters are placed inside sealed envelopes. The envelopes are numbered, and individuals randomly select envelopes until the final sample size is reached.
Blinding (investigator's opinion)
Not 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, School of nursing and midwifery, Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Bahonar Street, Mashhad, Razavi Khorasan Province
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۱۷۷۹۴۳۷۰۷
Approval date
2025-03-12, 1403/12/22
Ethics committee reference number
IR.MUMS.NURSE.REC.1403.096

Health conditions studied

1

Description of health condition studied
Colorectal cancer
ICD-10 code
C26.9
ICD-10 code description
Malignant neoplasm of ill-defined sites within the digestive system

Primary outcomes

1

Description
Fatigue score on the cancer fatigue scale
Timepoint
Fatigue measurement at baseline (pre-intervention) and endpoint (post-intervention, after the last intervention session).
Method of measurement
Cancer fatigue scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Transcutaneous Electrical Nerve Stimulation (TENS) group. The TENS intervention will be performed by the researcher and research assistant (female patients) to electrically stimulate sensory nerves in the lower back and back of the legs using a Berjis ST90 device. The current intensity will be tolerable for the patient, and the frequency will be 100 Hz. This will be conducted for 30 to 45 minutes in 4 sessions. Two sessions will be held on 2 consecutive days during one chemotherapy cycle, and the subsequent 2 sessions will be held on 2 days during the next chemotherapy cycle, which is scheduled every other week.

Category
Treatment - Devices

2

Description
Intervention Group 2: Acupressure group. Pressure will be applied to the points ST-36, LR-3, GB-20, TW-5 until the patient experiences pain, then the pressure will be slightly reduced. This will be done for 2 to 5 minutes at each point for 2 weeks (14 sessions) daily, during the intervals of 2 consecutive chemotherapy cycles, which are scheduled every other week. The patient will be trained by the researcher and research assistant (female patients) who have completed relevant training under the supervision of a Traditional Chinese Medicine specialist in the first 2 sessions. The remaining acupressure sessions (12 sessions) will be performed by the patient and followed up via telephone.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital, Ghaem Hospital, Omid Hospital

Full name of responsible person
Tayyebeh Pourghaznin

Street address
Boostan Enghelab Dormitory, Campus of Medical Sciences University, Bahar Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۳۷۰۷

Phone
+98 915 423 1632

Email
matin09307@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Tayyebeh Pourghaznein

Street address
Mashhad University of Medical Sciences, Bahar Street

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۷۷۹۴۳۷۰۷

Phone
+98 915 423 1632

Email
matin09307@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Matin Abdollahi

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Number 7, Bozorgmehr Alley, Molana Sharghi Street,Taybad town

City
Mashhad

Province
Razavi Khorasan

Postal code
9591784691

Phone
+98 915 423 1632

Email

matin09307@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Matin Abdollahi

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
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Phone
+98 915 423 1632

Email
matin09307@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Matin Abdollahi

Position
Master's student

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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
All data obtained from the collected questionnaires will be shared.

When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Using data to reduce disease complications Using data to improve patient outcomes Using data to advance science

From where data/document is obtainable
Matin Abdollahi Tel. No. 00989154231632 Email matin09307@gmail.com

What processes are involved for a request to access data/document
The email will be responded to within a maximum of one month regarding the terms of use of the data. The summary of the plan must be provided to the responsible person in an academic format.

Comments