

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Clinical trial study The effect of diaphragmatic breathing on pain, sleep and fatigue in patients with metastatic gastrointestinal cancers

Protocol summary

Study aim

Determining the effect of diaphragmatic breathing on pain, sleep and fatigue in patients with metastatic gastrointestinal cancers

Design

Clinical trial with control group, with a simple random method, participants are randomly assigned to two groups of intervention and control using a card. There are 22 participants in each group.

Settings and conduct

The place of study is oncology wards and preferably in the hospital room. Patients breathe diaphragmally sitting or lying down in bed, depending on their comfort.

Participants/Inclusion and exclusion criteria

Login: Satisfaction for cooperation. Diagnosis of metastatic gastrointestinal cancer. Age 18-50 years. Periodic experience of pain, sleep disturbance and unusual fatigue. Exit: Death. Discharge. Drug abuse. Patients with Glasgow coma less than 7

Intervention groups

In the intervention group, diaphragmatic breathing will be performed twice a day for 10 minutes for 10 minutes. There is no intervention in the control group.

Main outcome variables

The main outcome of the study is pain relief, improved sleep, and reduced fatigue.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053628N1**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

martam rezaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3427 6303

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial study The effect of diaphragmatic breathing on pain, sleep and fatigue in patients with metastatic gastrointestinal cancers

Public title

The effect of diaphragmatic breathing on pain, sleep and fatigue in patients with metastatic gastrointestinal cancers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction for cooperation
Diagnosis of metastatic gastrointestinal cancer based on the opinion of the treating physician
Age 18-50 years
No history of drug use
No history of debilitating musculoskeletal diseases
Periodic experience of chronic pain based on the tools of Van Korf et al
Periodic fatigue experience based on Piper tools
Periodic experience of sleep disorders based on the Petersburg instrument

Exclusion criteria:

Death during the intervention period
Discharge from the oncology department during the intervention period
Decreased consciousness so that they are unable to continue cooperating during the intervention period

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple random method using a card will be used. 2 types of cards A and B A total of 44 cards that Where 22 cards A and 22 cards B and then the participant randomly picks up one of the cards and is placed in one of the control or test groups. The people who take the A card are in the test group and the rest are in the control group. Individuals in the experimental group are trained and breathing exercises are performed, but there is no training or intervention in the control group. The researcher registers the people and assigns them to the test and control groups in a simple random way with a card.

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 of Kermanshah University of Medical Sciences

Street address

in front of Imam Ali Hospital, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6714895664

Approval date

2022-01-11, 1400/10/21

Ethics committee reference number

IR.KUMS.REC.1400.759

Health conditions studied

1

Description of health condition studied

Metastatic cancers of the gastrointestinal tract

ICD-10 code

C15-C26

ICD-10 code description

Malignant neoplasms of digestive organs

Primary outcomes

1

Description

The primary consequence is a pain management plan.

Timepoint

Before the intervention and after 10 days

Method of measurement

Visual Analogue Scale. Chronic Pain Questionnaire by Van Korf et al.

Secondary outcomes

1

Description

The secondary outcome variable is improved sleep seeking pain relief.

Timepoint

Before the intervention and then 10 days after the intervention .

Method of measurement

Petersburg Sleep Quality Questionnaire.

2

Description

The secondary outcome variable of fatigue recovery seeks pain relief.

Timepoint

Before the intervention and then 10 days after the intervention .

Method of measurement

Piper Fatigue Scale Questionnaire.

Intervention groups

1

Description

"Intervention group": Intervention group: In the intervention group, diaphragmatic breathing will be performed for 10 days and twice a day (9 am and 9 pm) for 10 minutes. Diaphragmatic breathing is basically done in both supine and sitting positions. Patients are instructed to lie down: Participants lie comfortably on the bed, focusing on the lower abdomen, bending the knees, and using pillows under the legs as needed. For a sitting position, the knees are bent and one hand is placed on the upper chest and the other hand on the lower chest. Place the immobile tongue in the floor of the mouth, relax by taking a deep breath and exhaling it slowly. . Hold your breath for 2-5 seconds and then exhale slowly through your mouth. It is best to calm the environment as much as possible to prevent distractions and avoid talking during the process.

Category

Other

2

Description

"Control group": There is no intervention in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Ayatollah Taleghani Hospital

Full name of responsible person

Maryam Rezaei

Street address

Unit9,Culture building, Moallem Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

50

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

Kermanshah University of Medical Sciences

Full name of responsible person

Maryam Rezaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

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Ph.D.

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Person responsible for updating data

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Position

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Latest degree

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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