

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The Effect of Foot Reflexology on Quality of Life in Patients with Chemotherapy-Induced Neuropathy in Colorectal Cancer who Admitted in Emam Hossein Hospital at Shahid Beheshti University of Medical Sciences in 1396

#### Protocol summary

##### Summary

The aim of this study was to investigate the effect of foot reflexology massage on the quality of life of patients with chemotherapy induced neuropathy in colorectal cancer patients admitted to Imam Hossein Hospital affiliated to Shahid Beheshti University of Medical Sciences Study Design: This study is an interventional and experimental. Study population: Patients with cancer who referred to Imam Hossein Hospital's oncology department Major entry criteria: Patients with colorectal cancer who are chemically treated with the specified regimens (taxans, platinum compounds, and vinca alkaloids). The diagnosis of colorectal cancer is done by a pathologist and cancer specialist. Neuropathy is diagnosed by a cancer specialist. Main criteria for withdrawal: Cause of any complications and illness in the patient's legs during the study Acute infectious diseases during the study Dismissing the patient and losing the research sample Sample size: 80 Intervention: Foot reflexology Time of intervention: Performing foot reflexology massage for 10 minutes for each leg and a total of 20 minutes for both legs in 4 periods of chemotherapy at intervals of 2 weeks Primary outcomes or outcomes of the study: Improving the quality of life

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017021632607N1**  
Registration date: **2017-08-04, 1396/05/13**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-04, 1396/05/13

##### Registrant information

###### Name

Hesam Gholamzadeh

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 938 413 0204

###### Email address

he.gholamzadeh@sbm.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

According to Shahid Beheshti University of Medical Sciences regulations

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Foot Reflexology on Quality of Life in Patients with Chemotherapy-Induced Neuropathy in Colorectal Cancer who Admitted in Emam Hossein Hospital at Shahid Beheshti University of Medical Sciences in 1396

## Public title

The Effect of Foot Reflexology on Quality of Life

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: Patients with colorectal cancer who are chemically treated with the specified regimens (taxans, platinum compounds, and vinca alkaloids); The diagnosis of colorectal cancer is done by a pathologist and cancer specialist; Neuropathy is diagnosed by a cancer specialist. Exclusion criteria: Cause of any complications and illness in the patient's legs during the study; Acute infectious diseases during the study; Dismissing the patient and losing the research sample.

## Age

From **18 years** old to **99 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Shahid Beheshti University of Medical Sciences,  
Faculty of Nursing and Midwifery

##### Street address

Shahid Beheshti University of Medical Sciences,  
Faculty of Nursing and Midwifery, Niayesh Crossroad,  
Vali Asr avenue, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2017-07-01, 1396/04/10

#### Ethics committee reference number

IR.SBMU.PHNM.1396.773

## Health conditions studied

### 1

#### Description of health condition studied

Colon and Rectum cancer

#### ICD-10 code

C19, C20,

#### ICD-10 code description

Malignant neoplasm of rectosigmoid junction, Malignant neoplasm of anus and anal canal, Malignant neoplasm of rectum

## Primary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before the intervention and at the next session immediately before the intervention, the questionnaires will be completed by the test group.

#### Method of measurement

European Organisation for Research and Treatment of Cancer quality of life questionnaires

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For intervention group, 4 sessions (two steps), foot reflexology massage (massage techniques and foot exercises) for 20 minutes, two weeks apart.

#### Category

Lifestyle

### 2

#### Description

The control group will receive standard cares of center.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Hossein medical and educational center

##### Full name of responsible person

Mahnaz Ilkhani, Ph.D. in Nursing, Assistant Professor

##### Street address

Tehran, Shahid Madani Avenue, Imam Hossein Hospital

##### City

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

DR Mahrokh Dolatian

**Street address**

Shahid Beheshti University of Medical Sciences,  
Faculty of Nursing and Midwifery, Niayesh Crossroad,  
Vali Asr avenue, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hesam Gholamzadeh

**Position**

MSN student

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahnaz Ilkhani

**Position**

DClinp in nursing

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Hesam Gholamzadeh

**Position**

MSN Student

**Other areas of specialty/work**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

**Data Dictionary**

*empty*