

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of Shiatsu massage on physiological parameters ,anxiety and pain during chemotherapy in patients with breast cancer

Protocol summary

Study aim

Evaluation of the effectiveness of Shiatsu massage on physiological index, anxiety and pain during chemotherapy in patients with breast cancer

Design

Clinical trial with control group, with parallel groups, Single blinded, randomized

Settings and conduct

In this study, 72 patients with breast cancer undergoing chemotherapy hospitalized in Ayatollah Khansari hospital in Arak city were selected and with random blocks will be divided to two groups of experimental and control. Alternate shiatsu will be performed for 5 minutes massage and 2-minute rest to 20 minutes by the intervention group, control group during this period will receive touch without pressure for 20 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cancer patients who have undergone at least one course of chemotherapy; age more than 18 and under 60, diagnosed with stage 2, 3, and 4 cancers at the discretion of the relevant physician; cancer patients with 6 months from the date of diagnosis exclusion criteria: Any life-threatening emergency situation ;skin diseases such as ulcers and infections of hand

Intervention groups

For the intervention group, during chemotherapy, a one-time Shiatsu massage will be performed on the Hugo spots for 5 minutes and 2 minutes of rest for up to 20 minutes. In the control group during chemotherapy, patients do not receive any intervention from the researcher for Shiatsu massage. In this group, only a touch without pressure will be performed for 20 minutes. The amount of pain, anxiety and physiological signs will be measured before and immediately after the intervention by tools and questionnaires.

Main outcome variables

Anxiety rate; Pain rate; Number of breaths; Blood pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151002024290N2**

Registration date: **2020-05-25, 1399/03/05**

Registration timing: **prospective**

Last update: **2020-05-25, 1399/03/05**

Update count: **0**

Registration date

2020-05-25, 1399/03/05

Registrant information

Name

Zohreh Farahani

Name of organization / entity

Arak Medical University

Country

Iran (Islamic Republic of)

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+98 86 3497 2718

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Shiatsu massage on physiological parameters ,anxiety and pain during chemotherapy in patients with breast cancer

Public title

The effect of Shiatsu massage in patients with breast cancer under chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Cancer patients who have been undergoing chemotherapy for at least one period. Age more than 18 and less than 60 years. Diagnosis of stages 2, 3 and 4 of cancer According to the relevant physician. Cancer patients with 6 months of diagnosis Full of consciousness No history of mental illness, seizures or epilepsy, asthma, thyroid disorder, olfactory disorder, severe heart failure that has been approved by a doctor No history of smoking and drug addiction Under chemotherapy with a special protocol

Exclusion criteria:

Paralysis of the hands

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the samples by random sampling method, they will be randomly and according to the table of random numbers in the two groups of test and control. In order to randomize the selection of 72 patients into two intervention and control groups, first 9 different blocks of 8 letters T and C are created, which indicate the intervention and control groups (4 people belonging to the intervention group and 4 people). Belong to the control group. These blocks are then randomly selected by drawing lots to obtain a 72-bit combination of blocks, respectively. The resulting combination of letters is placed one by one in 72 closed envelopes, respectively, and with the visit of each patient, one envelope is opened in order to determine in which group the patient is placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

It should be noted that the nurse who will measure vital signs and the level of anxiety and pain of the patient through the Spielberger questionnaire tool and the visual scale of pain will be unaware of the type of intervention being performed

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of medical sciences

Street address

Arak, Basij Square, Campus University of Medical Sciences Campus, School of Nursing

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2019-08-06, 1398/05/15

Ethics committee reference number

IR.ARAKMU.REC.1398.091

Health conditions studied**1****Description of health condition studied**

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Anxiety

Timepoint

Measure the amount of anxiety before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention.

Method of measurement

Spielberger Questionnaire

2**Description**

Pain

Timepoint

Measure the amount of pain before each chemotherapy

treatment with the intervention and immediately after each chemotherapy treatment with the intervention.

Method of measurement

Visual analog scale

3

Description

Blood pressure

Timepoint

Measure the amount of blood pressure before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention

Method of measurement

Mercury blood pressure device

4

Description

Number of heartbeats

Timepoint

Measure the amount of number of heartbeats before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention

Method of measurement

Cardiac and pulmonary monitor device

5

Description

Number of breaths

Timepoint

Measure the amount of number of breaths before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention

Method of measurement

Cardiac and pulmonary monitor device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, during chemotherapy, a one-time Shiatsu massage will be performed on the Hugo spots for 5 minutes and 2 minutes of rest for up to 20 minutes. The amount of pain, anxiety and physiological signs will be measured before and immediately after the intervention by tools and questionnaires.

Category

N/A

2

Description

Control group: Patients in the control group do not receive any Shiatsu massage intervention on the part of the researcher. In this group, only touch without pressure will be done for 20 minutes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khansari Hospital

Full name of responsible person

Zohreh Farahani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Postal code

3848176941

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Email

z.f.h.nursing@gmail.com

Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Zohreh Farahani

Position

Academic Instructor Faculty Of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

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Province

Markazi

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